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14. ABSTRACT
This project is broken into three focus areas: robotic curriculum, telesurgery, and simulation. In each we are exploring various applications and extensions of the existing robotic surgical systems. Under robotic curriculum we are bringing together the leading surgeons and academicians to define the outcomes measures, curriculum, and high stakes testing that should be used to certify surgeons who wish to practice robotic surgery. Under telesurgery we are exploring the ability to perform telesurgery using a robot within a metropolitan area based on the currently available technology. Under simulation we are examining the impact of rehearsing a procedure in a simulator immediately before performing that same procedure on a patient. This area also includes a comparative evaluation of all of the robotic simulators that are available with a recommendation of the best fit for military surgeons.

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Introduction

This project is broken into three focus areas: robotic curriculum, telesurgery, and simulation. In each we are exploring various applications and extensions of the existing robotic surgical systems. Under robotic curriculum we are bringing together the leading surgeons and academicians to define the outcomes measures, curriculum, and high stakes testing that should be used to certify surgeons who wish to practice robotic surgery. Under telesurgery we are exploring the ability to perform telesurgery using a robot within a metropolitan area based on the currently available technology. Under simulation we are examining the impact of rehearsing a procedure in a simulator immediately before performing that same procedure on a patient. This area also includes a comparative evaluation of all of the robotic simulators that are available with a recommendation of the best fit for military surgeons.

Statement of Work

ORIGINAL STATEMENT OF WORK

There are three primary areas of this research: Telesurgery, Simulation, and Robotic Curriculum. (1) The telesurgery project will identify the characteristics of latency during telesurgery and investigate the application of principles of automatic surgery. (2) Under simulation, we will validate a simulator that can be used by military surgeons to maintain their robotic skills while deployed. We will then use this device to explore the feasibility of surgical rehearsal as a potential solution to the latency issue in telesurgery. (3) We will organize robotic surgery experts to develop a nationally accepted curriculum in the Fundamentals of Robotic Surgery (FRS).

Period 1

Telesurgery: Communications Latency Experiments. Identify communication latency, measure safe latency levels for each robotic movement, modify surgical procedures to be effective in this environment.
Milestone: Telesurgery latency experiment report. Award + 270 days

Simulation: Military-use Validation. Validate a robotic simulator for maintaining the robotic surgery skills of deployed military surgeons.
Milestone: Robotic simulator validation report. Award + 210 days

Robotic Curriculum: Consensus Conferences. Organize and host conferences of approximately 40 leading robotic surgeons from around the United States to include military surgeons. Identify the fundamental knowledge and skills that should be a foundation for every robotic surgeon.
Milestone: FRS consensus conference reports. Award + 180 days and 365 days

Period 2

Telesurgery: Automatic Surgery. Apply movements recorded in a robotic simulator to actual execution with the da Vinci robot on solid models. Explore ability to automatically execute surgery from a simulator recording.
Milestone: Automatic surgery experiment results. Award + 730 days

Simulation: Surgical Rehearsal. Experiment with the effectiveness of simulated surgical rehearsal on improving the outcomes of robotic surgery.
Milestone: Surgical rehearsal experiment results. Award + 540 days

FRS Curriculum Validation and Transition. Develop specific training tasks and passing criteria for the FRS curriculum. Process the curriculum through the certifying bodies.
Milestone: Telesurgery medical procedure results. Award + 730 days

Executive Summary

Telesurgery: Communications Latency Experiments. As of August 30, 2012, 84 subjects have participated in this experiment. We continue to collect subject data. The data collected in the experiment has shed light on a number of details around robotic surgery. In general we find that the effect of latency on individual surgeons is not predictable by their levels of experience in either robotics or laparoscopy. The performance under latency varies widely at all latency settings and all levels of surgical experience. The majority of subjects, though not all, can manage latency at 200ms and below. Above this, most subjects of all experience levels exhibit severe drops in performance. Previous research projects have suggested that latency below 250ms could be considered manageable because it is below the perception threshold of most people. Our experiments agree with this for a majority of subjects, though certainly not for all.

The data collected during this experiment also allowed us to study the relationship between years of laparoscopic experience and performance in a robotic environment. We found a consistent negative correlation between these two variables. It appears that extensive laparoscopic experience is detrimental to the acquisition of skills in robotic surgery.

Papers on both of these results have been submitted for presentation at conferences and are being prepared for journal publication.

Simulation: Military-use Validation. At the project kick-off of this grant in September, 2011 we requested to move this experiment to year two of the grant. This was motivated by the lead time to purchase the necessary equipment. This change was accepted by the government and this project will be performed in the second year.

Robotic Curriculum: Consensus Conferences. We have held three conferences of leading robotic surgeons from around the world. Eighteen participated in the outcomes measures meeting, forty participated in the curriculum development meeting, and twenty-four participated in the curriculum writing meeting. We have identified a list of 25 outcomes measures that robotic surgeons need to be able to demonstrate. Three different curriculums have been created – didactic, psychomotor skills, and team training. A multi-skills device for testing many of the outcomes has been designed and will be produced in the second year.

We are in discussions with SAGES to develop a High Stakes Test for this material and to create a system to administer that test.

Simulation: Surgical Rehearsal. At the government kick-off meeting we requested to move this experiment to year one in place of the military-use validation study. Approval for that change was given by the government. Multiple protocols were designed for conducting this experiment; however, none of them were both feasible for implementation and acceptable to the government reviewers. A new protocol is in draft now and will be presented to the government for review at the end of September 2012. A brief summary of that protocol is included in this report, but has not been completed or approved at this time.

Telesurgery: Communications Latency

This experiment investigates the impact of communication latency on robotic surgical performance, where latency is quantitatively defined as length of time (in milliseconds) for the computer command from a surgeon‟s hand movement to be transmitted to the robot end effectors, and for the image of that movement to return to the surgeon‟s video display system. In this experiment we are interested in the effect that latency has on the completion time of the entire surgical tasks presented and the effect on the number of errors that are induced on the patient.

This is a prospective, randomized, observational study. We simulated different communication latencies ranging from 0 to 1000 milliseconds (ms) sequentially in 100 ms increments. We randomly assigned a different latency to each subject for each trial. In order to avoid repetition, the randomized latency used a block design so that latency values were all used before the set is used again. This assignment insured that: 1) each subject received a random latency for their exercises, and 2) each latency level has roughly equal number of observations (i.e. the observations will equally cover all situations).

One trial consisted of the following sequence of activities:

1. Acquaintance Period. The subjects walked through the curriculum of 4 tasks on the robot/simulator. They were allowed to get acquainted with the simulator controls.
2. Baseline Case. The subject performed a single complete trial with no latency in the system. The zero latency (0 ms) case provided a baseline performance of the subject for later comparison. It also provided a set of data useful for analyzing performance in a standard robotic environment.
3. Short term adaptation. Prior studies (Rayman et al 2005, 2006), have shown that subjects improve their performance in a latency environment over three different repetitions before plateauing at their long-term performance level on the fourth repetition. We selected the latency level for the subject and allow them to perform four tasks to move past the short-term learning curve phase.
4. Trial Case. Finally, we allowed the subject to perform the specified tasks that compose a single trial. This repetition is their long-term performance level. This trial is the one that is included in the statistical analysis of the study.

Experimental Tools

The latency effect is created using the dV-Trainer simulator (Figure 1) of the da Vinci surgical robot (Hung, 2011; Kennedy 2009). The simulator allows the insertion of specific levels of controlled latency so that the user‟s physical movements are not manifest by the simulated instruments until after the defined latency period has elapsed. The simulator does not have the ability to separately define the latency of messages traveling surgeon-to-robot and robot-to-surgeon.

Figure 1. dV-Trainer Simulator (Mimic Technologies, Inc.)

During actual telesurgery, the messages sent between the surgeon's machine and the remote patient station will be delayed due to the speed of light and the message routing that occurs on the internet. Determining how much latency can be safely tolerated in surgery is an important question (Anvari, 2005 and 2007). This experiment hypothesizes that there are two distinct thresholds of performance under increasing latency. The first is the level of latency at which a surgeon can first detect that his or her movements are being affected by the communication link. Communication latency lower than this level is consciously imperceptible and potentially non-invasive to the surgical procedure. Hence, if such levels can be achieved in the real world, then telesurgery may be safe for human surgery right now. The second level is the point at which the surgeon's performance is degraded to the point that the surgery cannot be performed safely (Marescaux, 2002; Lum, 2009). This level is identified through both simulator measured performance and the expert opinion of the surgeon. Between the first and second thresholds, a surgeon may be able to successfully manage the effects of latency and perform a safe and successful procedure. Beyond the second threshold, telesurgery would be considered unsafe with the available equipment (Figure 2).

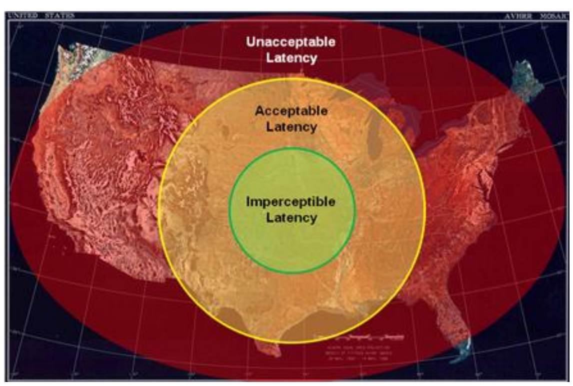
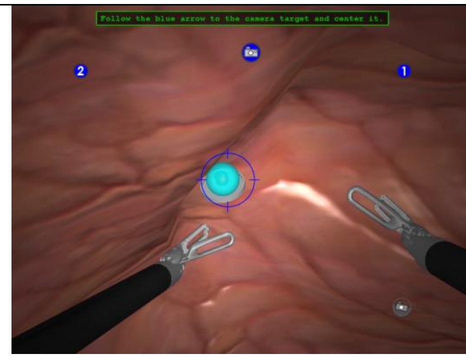
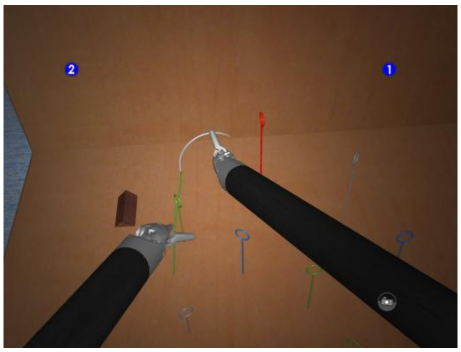


Figure 2. Conceptual Diagram of Communication Latency Thresholds.

(a) Pegboard 1



(b) Camera Targeting


(c) Thread the Rings

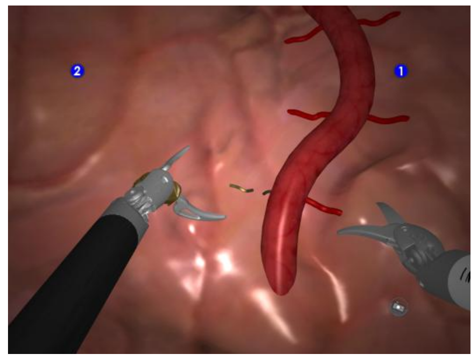

(d) Energy Dissection

Figure 3. Simulated Surgical Skills Tasks

We further hypothesize that more experienced surgeons will be more successful at managing the effects of latency and would be the best practitioners for this extension of robotic surgery. If this hypothesis is correct, then surgeons with more experience should achieve higher scores and shorter completion times in the simulation experiment that we are performing.

In this experiment, subjects performed the four simulated surgical skills exercises shown in Figure 3. These represent many of the core skills that are required in robotic surgery. Each subject performed each exercise three times as described above.

Data Collection

Experimental data was collected by the simulator software and manually via questionnaires. Research proctors administered a Pre-Test questionnaire on the level of surgical experience and related activities of the subject. All personal and performance data was anonymized to insure that the identity of the subject could not be linked to the data that was collected. The proctors also administered a Post-Test questionnaire at the conclusion of each of the skills exercises during the final performance stage. The simulator software automatically collected multiple measures of the subject"s performance. This provided data for all subjects at zero latency, during their familiarization stage with latency, and during the final stage which is the focus of the analysis. This data will allow us to perform multiple analyses of the skills of robotic surgeons both with and without communication latency.

Pre-Test Questionnaire

The Pre-Test questionnaire identified multiple items of demographic, experience, and practice data on the subjects. These included: age, gender, dominant hand, surgical status, years of surgical experience, years

of laparoscopic experience, years of robotic experience, number of weekly procedures in laparoscopy and robotics, and experience with laparoscopic and robotic simulators, as well as with video games and musical instruments. Additional questions captured their opinion on the use of simulation in surgical education and certification.

This data was then matched to the data from their performance in the simulator.

Simulator Performance

During the experiment, the simulator itself collected a number of data points on each subject‟s performance. These included: time to complete, overall score, total hand motion in centimeters, master working space, number of instrument collisions, number of items dropped, excessive instrument force, distance instruments out of view, incorrect use of electrical energy, simulated blood loss, and number of broken blood vessels.

Post-Test Questionnaire

As the subjects completed their final repetition of each of the four skills exercises, the proctor administered a post-test questionnaire which asked the subject for their opinion on the stress induced by the simulation with latency. This included measures of the mental and physical demands of the task, the pace of the task, their opinion on their level of success, the amount of effort expended, the level of mental discouragement experienced, and their perceived complexity of the exercise.

Results

The analysis of data from the first 54 subjects is provided here. Of the 54 subjects who began the experiment, several were unable to complete all of the tasks due to the limited amount of time that they could devote to the experiment. Others found the experiment too taxing and elected to terminate their participation before completion. As a result, we collected complete data sets without latency on 42 subjects and complete data with latency on only 21 of those subjects.

This data was analyzed to determine the level of correlation between the subjects‟ experience and their performance both with and without latency. For the non-latency sample size of 42 and alpha=0.05, the Pearson Product Moment Correlation (PPMC) value is 0.304. This means that for a correlation coefficient of two variables in this size of sample to be significant, it must be larger than the PPMC value.

Table 1. Correlation Coefficients without Latency

Exercise	Overall Score	Time to Complete
Pegboard 1	0.141	-0.110
Camera Targeting	0.201	-0.173
Thread the Rings	0.156	-0.225
Energy Dissection	0.267	-0.217

In an environment without any latency imposed we found a positive correlation between years of robotic experience and overall performance score, as well as a negative correlation between experience and the total time to complete the exercise (Table 1). Both of these indicate that more experience leads to better performance in the simulator without latency. Though this correlation is consistently supportive that surgeons with more experience perform non-latency exercises better than those with less experience, the

degree of this correlation is not large enough to be statistically significant for this sample size. The data for the pegboard exercise is graphed in Figures 4 and 5.

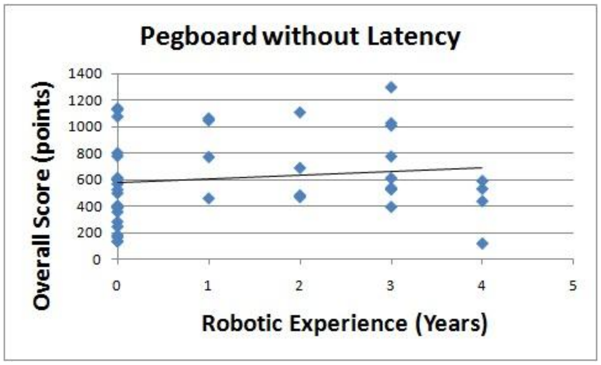


Figure 4. Correlation between Robotic Experience and Overall Score for the Peg Board exercise without communication latency.

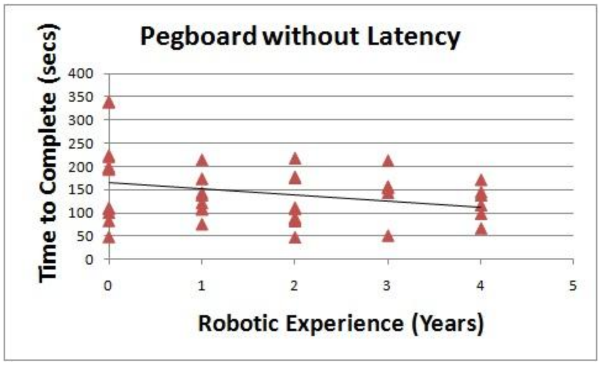


Figure 5. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise without communication latency.

When latency is added, the subjects with similar treatments are in much smaller numbers. For example, at a latency of 400ms we have 4 or 5 data points for each exercise as shown in Table 2. The analysis of this data with alpha=0.05 requires a PPMC of 0.811 or 0.754 (respectively) to achieve significance. For this small number of data points, the level of experience does not contribute to the ability of the surgeon to perform better under latency. The data for the pegboard exercise at various latency levels is graphed in Figures 6 and 7, illustrating the lack of a trend for both surgeon experience and latency levels. However, the number of data points at each latency level is still so small that definitive conclusions cannot be made about the issue.

Table 2. Correlation Coefficients with 400ms Latency

Exercise	n	Overall Score	Time to Complete
Pegboard 1	5	0.093	0.187
Camera Targeting	4	-0.915	0.583
Thread the Rings	4	-0.330	0.262

Energy Dissection	5	0.239	0.961

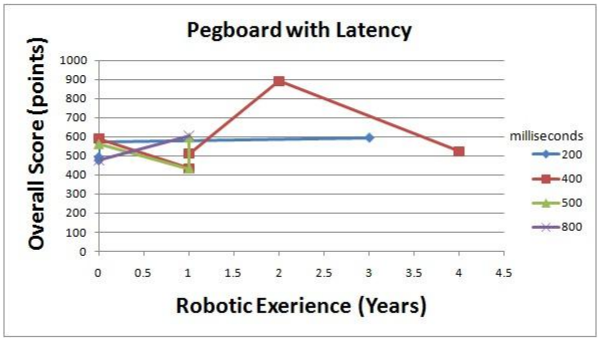


Figure 6. Correlation between Robotic Experience and Overall Score for the Peg Board exercise with various communication latencies.

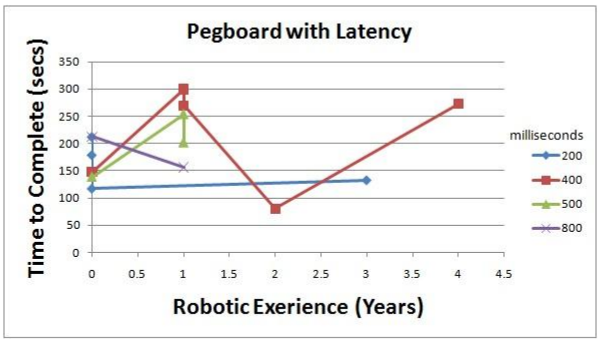


Figure 7. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise with various communication latencies.

The data suggests that surgeons who have more experience in robotic surgery are not better equipped to self-manage the challenges presented by communication latency in telesurgery. Subjects with little experience are as likely to successfully manage latency as are surgeons with more experience.

This same trend holds when comparing independent variables like total surgical experience and laparoscopic experience to the scores achieved in the simulator with latency.

Conclusions

The lack of correlation between experience and telesurgical performance under latency refutes our original hypothesis that a more experienced surgeon would more successfully manage the effects of latency. This negative finding has led to speculation on the cause of these results. Several may be possible, but each will require additional experimentation. First, experienced surgeons may be very talented, but fixed, in their methods of performing surgery. This may lead them to perform poorly under latency because it is difficult for them to modify their behaviors, where inexperienced surgeons are less ingrained and more adaptable to the situation. Second, since the simulator is a computer-generated virtual environment, it is possible that surgeons who have more experience in simulators, virtual worlds, and computer games may have developed a proficiency for solving problems in this kind of environment. They may also have experienced latency in those environments and developed techniques for compensating for it. Third, the ability to manage latency may be related to the physical and biological wiring of an individual. This could be a similar phenomenon to the tendency for some people to

experience simulator sickness, while others do not suffer from it. These speculations are worthy of further investigation.

Our experience with subjects has been that latency levels above 500ms severely degrades the performance of all subjects. In many cases they become so frustrated or exhausted that they terminate their participation before completion. This behavior has resulted in a loss of a number of valuable data points and it detracts from the number of subjects who can be assigned to latency levels at or below 500ms where we have found the best results. As a result, we have modified the experiment to eliminate the use of latency levels over 500ms. As we continue the experiment we will be able to collect more data at lower latency levels where the most interesting and useful results seem to reside. This modification will require an adjustment to our statistical analysis in order to accurately represent results across this change.

The objective of this analysis was to identify the degree to which a surgeon can compensate for the effects of latency that are present in a telesurgery environment. The long-term goal is to identify the thresholds where safe and successful surgery can be performed. Our findings at this point refute our hypothesis that more experienced surgeons would be able to manage latency more successfully. In the data collected there is no correlation between robotic experience and the ability to achieve a higher score in the simulator when latency is inserted into the procedure.

Robotic Surgery: Laparoscopic Experience and Robotic Performance

There is some question as to the degree to which experience in laparoscopy supports superior performance in robotic surgery. Using the data collected in the telesurgery experiment we examined the relationship between experience in laparoscopy and performance on skills exercises in a robotic simulator with the goal of determining whether the correlation is positive or negative.

Methods

Surgeons were tested in their ability to perform four different simulated robotic surgical skills using the dV-Trainer simulators (Mimic Technologies, Inc., Seattle, WA) of the da Vinci surgical robot (Intuitive Surgical Inc., Sunnyvale, CA). The subjects completed a pre-test questionnaire to provide demographic and experience data, which included the number of years of practice in both laparoscopic and robotic surgery. The simulator collected multiple performance metrics during each of the four exercises. Pearson"s correlation was computed on the relationship between the number of years of laparoscopic and robotic experience, and their overall proficiency score, with control for the correlation between lap and robotic experience.

Results

A total of 54 subjects participated in the experiment and 42 completed all four experimental tasks. These subjects reported a range of experience in laparoscopic surgery between 4 and 34 years, and in robotic surgery between 0 and 11 years. For this analysis those indicating zero years of robotic experience were omitted, reducing the sample size to 30 surgeons. Using a Pearson Correlation (df=28, alpha=0.05, and significance threshold of 0.349) we found a statistically significant negative correlation between years of laparoscopic experience and the overall proficiency score in two of the four robotic surgery exercises (pegboard = -0.361; thread rings = -0.454), and a negative correlation which did not achieve statistical significance in the two remaining exercises (peg board = -0.152; energy dissection = -0.228). This data refuted our initial assumption that more years of laparoscopic experience would indicate higher levels of proficiency in robotic skills. The data shows a consistent negative correlation between these variables. We checked for a possible negative correlation between the number of years of laparoscopic and robotic surgical experience, which would indicate that surgeons with more laparoscopic experience consistently have less robotic experience and vice versa. However, the correlation between those two variables was 0.067, indicating almost no correlation between the two.

Conclusions

Using a simulator to measure the proficiency of surgeons with both laparoscopic and robotic surgical experience we found a negative correlation between the number of years of laparoscopic experience and proficiency the exercises. Surgeons with more experience in laparoscopy performed worse on exercises in a robotic simulator device than those with less experience in laparoscopy. This analysis suggests that years of laparoscopic experience may be detrimental to the development of expertise in robotically-assisted MIS.

This study was based on performance with a dV-Trainer (Mimic Technologies, Seattle, WA) simulator of the da Vinci robot (Intuitive Surgical, San Jose, CA). It is possible that the differences between the simulator and the real robot could contribute to poor performance with the device which would not be present if we were using the actual robot. Analysis of our data showed a positive correlation between the surgeons" years of robotic surgery and their overall scores with the simulator, suggesting that direct experience with robotics does contribute to better performance with the simulator device. Though positive, this correlation did not reach the threshold for significance (0.456) for this sample

Surgical Rehearsal

Surgical rehearsal is a relatively new concept in the medical literature. The aim of its introduction to the surgical field is to improve surgical performance, outcomes and ensure patient safety. However, it is imperative to differentiate between "simulation" in general and surgical rehearsal since the later is a "patient-specific simulation" which gives the opportunity to rehearse the procedure in a simulated environment, using the real patient's data, prior to performing the intervention on the patient rather than exercising general surgical tasks, which is mere simulation. These two training modalities can utilize a simulator.

A number of simulators have been developed to support training and skill assessment in robotic surgery. The currently available simulators include: the Skills Simulator by Intuitive Surgical Inc., aka the "Backpack Simulator", the dV-Trainer from Mimic Technologies Inc., and the RoSS by Surgical Sciences Inc. All of these simulators utilize a visual scene that is presented in a computer generated 3D environment that represents challenging tests of dexterity and machine operations. In the first simulator, the trainee sits at and operates a console that is identical to the console in the da Vinci surgical system, just as if she or he were doing a surgery. Whereas the second utilizes a desktop device that replicates the hardware of the da Vinci surgical system surgeon‟s console, it includes a 3D simulated environment that is identical to the former software. The third is similar in that it uses a simulated hardware device in place of the real robotic equipment.

"Personalization" of the surgical procedure implies the conversion of a digital CT scans (or other radiological images) into a Virtual Reality (VR) system that is interactive within the simulator system to the surgeon‟s intervention. This system creates a 3D reconstruction of the organ and the surgeon can rehearse a single step or a complete surgery (Anvari, 2004). Unfortunately, this is not currently available in the robotic simulators and is considered a rate-limiting step toward any effort to study robotic surgical rehearsal (Satava & Simon, 1993). However, this type of simulation has been performed in laparoscopic surgery (Willaert et al, 2010) and may be available for use in robotic simulation in the near future.

[Note: The following experiment is still in draft protocol development and has not yet been approved by the government sponsor.]

Given the current state of simulator technology, it is possible to perform near identical procedures only when using skills devices with the robot which already exist within the virtual models of the simulators. For the purposes of this research, we will use a simulator, a skills device, and a porcine model. The dV-Trainer contains a number of exercises, two of which can be leveraged for this study. The simplest experiment will compare performance on an existing skills exercise called the "Matchboard". Subjects will perform this exercise in the simulator for rehearsal. After a given number of repetitions, or upon achieving proficiency (protocol is still under design), they will move to the actual da Vinci robot and perform this identical skill using a Matchboard object that has been manufactured to the exact dimensions and specifications of the VR object in the simulator (Figure 8). The performance of this group will be compared to a control group who receives instructions on performing the exercise on the robot, but who will attempt it without experience in the simulator.

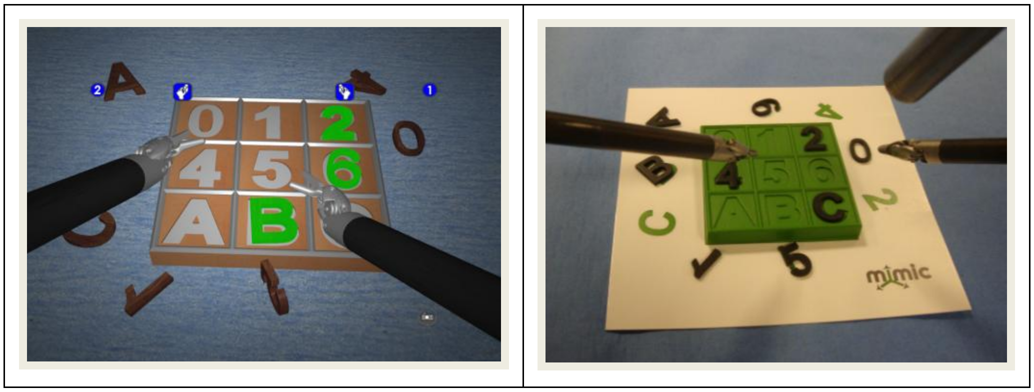


Figure 8. Dry Lab Surgical Rehearsal Experiment

A more complex version of this experiment has been designed which compares performance on the simulator with performance on a live porcine model. The current simulators contain a limited number of exercises that approximate live tissue operations. The companies that make these devices have stated that they are not presently prepared to create a more animate exercise in their simulators. Therefore, we have identified an Energy Dissection exercise in the dV-Trainer for which there is a rough equivalent in a porcine model (Figure 9). The experimental group will rehearse the exercise in the simulator and then perform an approximately equal procedure in the porcine model. Their performance will be compared to that of a control group who will operate on the porcine model after instruction on the procedure, but without experience on the simulator.

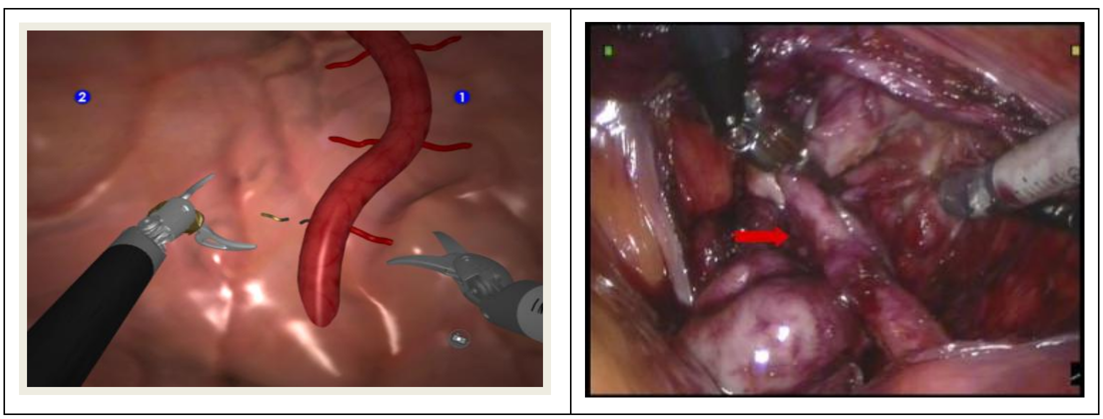


Figure 9. Wet Lab Surgical Rehearsal Experiment

The data from both of these experiments will be analyzed to measure the difference in performance for subjects who receive a simulation rehearsal prior to performing a nearly identical task with the real robot. This data will inform the community on the potential for using simulators as pre-operative planning and rehearsal systems. Other researchers have conducted experiments on the effects of generic warm-up exercises with the simulator. Surgical rehearsal extends that concept to a procedure specific activity which will eventually become a realistic representation on surgery on CT images of the patient‟s personal anatomy.

Robotic Curriculum

We are collaborating with a grant to the Minimally Invasive Robotics Association (MIRA) to create a fundamental curriculum in the field of robotic surgery. Following the process and lessons learned from the creation of the Fundamentals of Laparoscopic Surgery (FRS), this joint project is referred to as the Fundamentals of Robotic Surgery (FRS).

Methods

This project has resulted in three meetings of leading robotic surgeons from around the world. As a group they have agreed upon a set of outcomes measures and a draft curriculum. They have also designed a multi-skills testing device for use in the psychomotor skills portion of the curriculum.

We have created a process and a group of participants to unify the previous attempts to develop a robotic curriculum and expand to a much larger foundation of surgical societies with a stake in this new technology.

Participation in this effort was invited from multiple certifying boards, professional surgical societies, and associations that represent international practitioners and regulators of various surgical specialties as well as the United States Department of Defense (DoD) and Veterans Health Administration (VHA) (Table 3). The conference participants are members of these organizations or agencies and are selected to be able to provide insight into the needs of their organizations, but they do not represent an endorsement or acceptance of the results, and participation does not imply acceptance by the societies, boards or agencies. However, the AUA, AAGL, and SAGES elected to appoint and send representatives who could officially speak for their organizations‟ needs for a robotic curriculum and officially accept the results of the consensus conferences. This project is an effort to provide the stakeholders with the best scientific evidence upon which to base their decisions regarding implementation of a fundamental curriculum to meet their needs while reducing redundancy, competition and duplication of effort.

Table 3. Invited Organizational Representation in Fundamentals of Robotic Surgery.

American Association Gynecologic Laparoscopy (AAGL) *
American College of Surgeons (ACS)
American Congress of Obstetrics and-Gynecology (ACOG)
American Urologic Association (AUA) *
American Academy of Orthopedic Surgeons (AAOA)
American Association of Thoracic Surgeons (AATS)
American Association of Colo-rectal Surgeons (ASCRS)
Minimally Invasive Robotic Association (MIRA) †
Society for Robotic Surgery (SRS)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) *
American Board of Surgery (ABS)
Accreditation Council of Graduate Medical Education (ACGME)
Association of Surgical Educators (ASE)
Residency Review Committee (RRC) – Surgery
Royal College of Surgeons-Ireland (RCSI)
Royal College of Surgeons-London (RCSL)
Royal College of Surgeons-Australia (RCSA)
U.S. Department of Defense (DoD) †
U.S. Department of Veterans Health Affairs (VHA)
* : Official Representative Participation
† : Funding organizations.

Each consensus conference was conducted over a two-day period using a modified Delphi Method (Dalkey, 1969). This methodology consisted of a facilitator who captured the input and guidance of the participants. This input was then analyzed for common concepts to create a list of critical items in robotic surgery. Previously published material from a single institution‟s curriculum was used as a template for initial idea generation (Dulan et al, 2012a, 2012b). The individual outcomes measures and curriculum materials were itemized and votes taken on their importance according to each participant. This method led to a composite ranking which was captured in a draft report. The report containing the first group ratings was then sent to each participant for their private deliberation. Each participant then submitted a second set of scores which were informed by the first composite scores, but anonymous to other group members. This modified Delphi Method led to a higher level of consensus around the measures and the curriculum. It also identified those items for which there was little group support. Those items were removed from the list of outcomes measures and from the outline of the curriculum.

The first conference on outcomes measures was attended by 20 participants that included surgeons, scientists, educators, and facilitators. The ranking of the tasks identified was done by a subset of nine experienced surgeons. Participants who were not surgeons abstained from the scoring process.
The second conference on curriculum development was attended by 38 surgeons, scientists, educators, and facilitators. This group reviewed and became familiar with the material from the first conference. Thereupon, they were divided into three working groups to develop curriculum that focused on didactic and knowledge-based information, psychomotor skills, and team training and communications. Similarly, the actual ranking of the material developed was limited to experienced surgeons within the group.

Results

The first consensus conference resulted in a list of 25 outcomes measures which the group agreed should be mastered by a surgeon seeking privileges in robotics. These included 8 pre-operative, 15 intra-operative and 2 post–operative tasks which are shown in Table 4. The resulting report also provides detailed definitions, descriptions, errors, outcomes and metrics for each of these tasks (Satava et al, 2012).

Table 4. FRS Outcomes Measures from Consensus Conference

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

The second consensus conference on curriculum development resulted in outlines and principles for the creation of a curriculum to teach the previously identified list of tasks and knowledge.

Didactic and Knowledge. The didactic and knowledge working group created an outline of the material which should be taught in lecture format. This will include:

1. Introduction to robotic surgical systems.
2. Pre-operative set-up of equipment and positioning of staff.

3. Intra-operative use of a robot, surgeon ergonomics, visual field control, and necessary instruments and supplies.
4. Post-operative steps for removing a robot and transitioning to bedside control.

Each of these included an explicit list of errors that can occur in the process.

Psychomotor. The psychomotor skills working group prefaced their work with seven principles that should be applied in selecting or designing a skills device for robotic surgery. Those principles were:

1. The tasks should be 3 dimensional in nature.
2. The tasks designed for testing should be such that they have multiple learning objectives that incorporate multiple tasks from the first conference report. The tasks designed for training will have more focused learning objectives.
3. Implementation of the tasks and the resultant method for teaching should be cost effective.
4. High fidelity models should be used for testing. Training can use lower fidelity devices or methods.
5. Tasks should be easy to administer to ensure Inter-Rater Reliability (IRR).
6. The tasks should be designed for implementation with physical objects and devices. Future implementation in VR with a simulator would be derivative of the physical model.
7. Preference should be given to tasks that have existing evidence of validity

The group then identified 16 of the 25 tasks which contained psychomotor features. To address these, they proposed ten tasks which could be used to measure these skills. Three tasks were drawn from FLS, others were selected from existing educational programs, and designs for new task devices were proposed.

1. FLS peg transfer
2. FLS suturing
3. FLS pattern cutting
4. Running Suture
5. Dome with four towers
6. Vessel dissection and clipping
7. UTSW 4th arm retraction and cutting
8. Energy and mechanical cutting
9. Docking task (new design)
10. Trocar insertion task (new design)

For each of these the group also identified the associated task description, conditions, metrics, and errors.

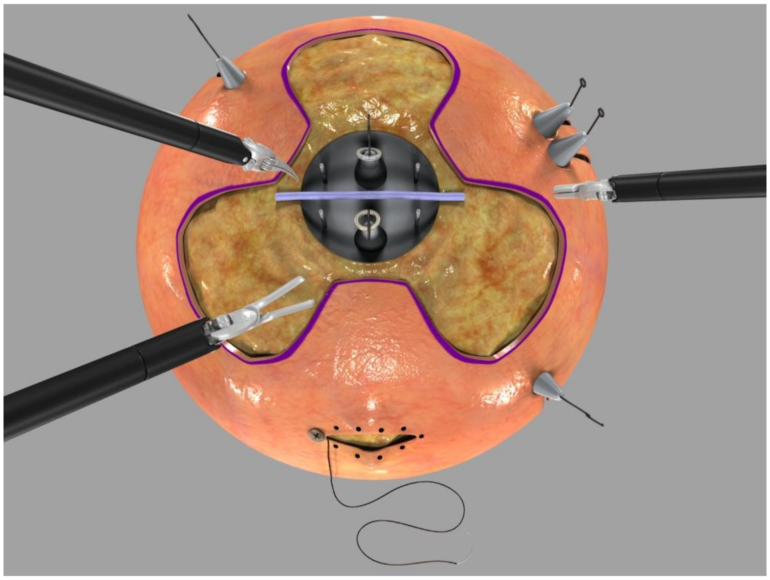


Figure 10: Design for FRS Psychomotor Skills Testing Device

Team Training and Communications. The team training and communications working group prefaced their work by defining the importance of team training in a robotic environment. They identified the following principles as essential to successful team-based operations and training.

1. Inclusion
2. Empowerment
3. Person specific
4. Reiterative
5. „Just in time"
6. Ownership
7. Risk management/quality improvement- closed loop

They stated that existing programs like TeamSTEPPS can be applied to robotic teams. Their curriculum follows a checklist format and is conceptually derived from the standard WHO checklist. For robotic training they recommended the following checklists:

1. Pre-operative. Addressing General situation, surgeon, anesthetist, nurse/OPD, and surgical site infection.
2. Robotic Docking. Addressing anesthesia, patient, bedside assist, procedure-specific checks, and trouble shooting.
3. Intra-operative. Addressing the communication that occurs within a team throughout the operation.
4. Undocking and Debriefing.

A third consensus conference was held in August 2012 to write the detailed material that to be included in the didactic and team training sections of the curriculum; and a specific psychomotor skills device was designed.

Conclusions & Discussion

Three consensus conferences involving members from major stakeholder organizations in surgical training, governance, and certification across multiple specialties have been conducted to arrive at a consensus regarding the most important outcome measures for the safe conduct of robotic surgery and the curriculum to teach those skills and knowledge. The development of FRS is multi-specialty, system

agnostic and follows decades of experience in other industries at developing such education and training platforms. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgery skills and is capable of passing the requirements of high stakes testing and evaluation. At some future time, this testing and evaluation would be administered by an appropriate independent, objective and authoritative organization, which would adopt the materials developed through this consensus process.

Participants

In addition to the two funding agencies, this project is a collaboration of leading robotic surgeons and educators. The following have all participated in and contributed to the creation of the materials reported here:

A. Advincula; R. Aggarwal; A. Al Ansari; D. Albala; R. Angelo; M. Anvari; J. Armstrong; G. Ballantyne; M. Billia; J. Borin; D. Bouchier-Hayes; T. Brand; S. Chauhan; P. Coelho; A. Cuschieri; B. Dunkin; S. Dunlow; V. Ficarra; A. Gallagher; L. Glazerman; T. Grantcharov; D. Hananel; J. Hebert; R. Holloway; W. Judd; K. Kim; M. Koch; T. Kowalewski; R. Kumar; K. Kunkler; G. Lee; T. Lendvay; R. Leveillee; J. Levy; G. Maddern; S. Magnuson; M. Marohn; D. Maron; M. Martino; P. Neary; K. Palmer; E. Parra-Davila; V. Patel; S. Ramamoorthy; K. Rha; J. Riess; B. Rocco; R. Rush; R. Satava; D. Scott; N. Seymour; M. Sinanan; R. Smith; D. Stefanidis; C. Sundaram; R. Sweet; E. Verrier; G. Weinstein

Key Research Accomplishments

- *Telesurgery: Communications Latency.* Performance under latency is not correlated with years of experience in robotics or laparoscopy.
- *Robotic Surgery Skills.* Extensive years of laparoscopic experience are detrimental to acquiring robotic surgery skills.
- *Robotic Curriculum: Consensus Conferences.* Outcomes measures and a curriculum for certifying robotic surgeons have been developed. Validation will be performed in the second year of the grant.
- *Simulation: Surgical Rehearsal.* A protocol for exploring the effects of procedure-specific simulation rehearsal on surgical performance is being developed.

Reportable Outcomes

Manuscripts

Satava, Chauhan, Smith, & Patel. “Fundamentals of Robotic Surgery Consensus Conference 1: Outcomes Measures”, *Surgery* (an ACS journal). Submitted April 2012.

Smith & Chauhan. “Using Simulators to Measure Communication Latency Effects in Robotic Telesurgery”, *2012 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2012.

Abstracts

Satava, Smith & Patel. “Report on the First Consensus Conference on the Fundamentals of Robotic Surgery” Outcomes Measures”, *ACS Accredited Education Institutes Meeting*. March 2012.

Presentations

Satava & Smith. “Fundamentals of Robotic Surgery (FRS): Overview and Results of First Two Consensus Conferences” Society for Laparoscopic Surgeons Annual Meeting, September 2012

Smith. “Robotic Surgery and Surgical Simulation”, presentation to *International Council on Systems Engineering – Orlando Chapter*. February 2012.

Smith. “Beyond Education and Training: Challenges of Running Medical Simulators in New Paradigms”. *International Meeting on Simulation in Healthcare*. January 2012.

Smith. "Simulation in Surgical Education", presentation to *American College of Healthcare Executives – Orlando Chapter*, December 2011.

Smith. "Medical Simulation Special Event: Robotic and Telesurgery Research Using Simulation", *Interservice/Industry Training, Simulation, and Education Conference*, December 2011.

Smith. "Robotic and Telesurgery Research", presentation to *National Center for Simulation – Quarterly Meeting*, October 2011.

Conclusion

Telesurgery: Communications Latency Experiments. As of August 30, 2012, 84 subjects have participated in this experiment. We continue to collect subject data. The data collected in the experiment has shed light on a number of details around robotic surgery. In general we find that the effect of latency on individual surgeons is not predictable by their levels of experience in either robotics or laparoscopy. The performance under latency varies widely at all latency settings. The majority of subjects, though not all, can manage latency at 200ms and below. Above this, most subjects of all experience levels exhibit severe drops in performance. Previous research projects have suggested that latency below 250ms could be considered manageable because it is below the perception threshold of most people. Our experiments agree with this for a majority of subjects, though certainly not for all.

The data from this experiment also allowed us to study the relationship between years of laparoscopic experience and performance in a robotic environment. We found a consistent negative correlation between these two variables. It appears that extensive laparoscopic experience is detrimental to the acquisition of skills in robotic surgery.

Papers on both of these results have been submitted for presentation at conferences and are being prepared for journal publication.

Simulation: Military-use Validation. At the project kick-off of this grant in September, 2011 we requested to move this experiment to year two of the grant. This was motivated by the lead time necessary to purchase the equipment required. This change was accepted by the government and this project will be performed in the second year.

Robotic Curriculum: Consensus Conferences. We have held three conferences consisting of leading robotic surgeons from around the world. Eighteen participated in the outcomes measures meeting, forty participated in the curriculum development meeting, and twenty-four participated in the curriculum writing meeting. We have developed a list of 25 outcomes measures that robotic surgeons need to be able to demonstrate. Three different curriculums have been created – didactic, psychomotor skills, and team training. A multi-skills device for testing many of the outcomes has been designed and will be produced in the second year.

We are in discussions with SAGES to develop a High Stakes Test for this material and to create a system to administer that test.

Simulation: Surgical Rehearsal. At the government kick-off meeting we requested to move this experiment to year one in place of the military-use validation study. Approval for that change was given by the government. Multiple protocols were designed for conducting this experiment; however, none of them were both feasible for implementation and acceptable to the government reviewers. A new protocol is in draft now and will be presented to the government for review at the end of September 2012. A summary of that protocol is included in this report, but has not been completed or approved at this time.

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Appendices

Copies of manuscripts, abstracts, and presentations of work resulting from this grant are included as appendices in separate documents.

Contribution of laparoscopic surgical experience to the development of robotic proficiency

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Abstract

Objectives: *There is some question as to the degree to which experience in laparoscopy supports superior performance in robotic surgery. This study examined the relationship between experience in laparoscopy and performance on skills exercises in a robotic simulator with the goal of determining whether the correlation is positive or negative.*

Methods: *Surgeons were tested in their ability to perform four different simulated robotic surgical skills using the dV-Trainer simulators (Mimic Technologies, Inc., Seattle, WA) of the da Vinci surgical robot (Intuitive Surgical Inc., Sunnyvale, CA). The subjects completed a pre-test questionnaire to provide demographic and experience data, which included the number of years of practice in both laparoscopic and robotic surgery. The simulator collected multiple performance metrics during each of the four exercises. Pearson's correlation was computed on the relationship between the number of years of laparoscopic and robotic experience, and their overall proficiency score, with control for the correlation between lap and robotic experience.*

Results: *A total of 54 subjects participated in the experiment and 42 completed all four experimental tasks. These subjects reported a range of experience in laparoscopic surgery between 4 and 34 years, and in robotic surgery between 0 and 11 years. For this analysis those indicating zero years of robotic experience were omitted, reducing the sample size to 30 surgeons. Using a Pearson Correlation (df=28, alpha=0.05, and significance threshold of 0.349) we found a statistically significant negative correlation between years of laparoscopic experience and the overall proficiency score in two of the four robotic surgery exercises (pegboard = -0.361; thread rings = -0.454), and a negative correlation which did not achieve statistical significance in the two remaining exercises (peg board = -0.152; energy dissection = -0.228). This data refuted our initial assumption that more years of laparoscopic experience would indicate higher levels of proficiency in robotic skills. The data shows a consistent negative correlation between these variables. We checked for a possible negative correlation between the number of years of laparoscopic and robotic surgical experience, which would indicate that surgeons with more laparoscopic experience consistently have less robotic experience and vice versa. However, the correlation between those two variables was 0.067, indicating almost no correlation between the two.*

Conclusions: *Using a simulator to measure the proficiency of surgeons with both laparoscopic and robotic surgical experience we found a negative correlation between the number of years of laparoscopic experience and proficiency the exercises. Surgeons with more experience in laparoscopy performed worse on exercises in a robotic simulator device than those with less*

experience in laparoscopy. This analysis suggests that years of laparoscopic experience may be detrimental to the development of expertise in robotically-assisted MIS.

This study was based on performance with a dV-Trainer (Mimic Technologies, Seattle, WA) simulator of the da Vinci robot (Intuitive Surgical, San Jose, CA). It is possible that the differences between the simulator and the real robot could contribute to poor performance with the device which would not be present if we were using the actual robot. Analysis of our data showed a positive correlation between the surgeons's years of robotic surgery and their overall scores with the simulator, suggesting that direct experience with robotics does contribute to better performance with the simulator device. Though positive, this correlation did not reach the threshold for significance (0.456) for this sample size.

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Simulation in Surgical Education:

Innovation to reduce training time, increase case access, increase expertise, and reduce errors

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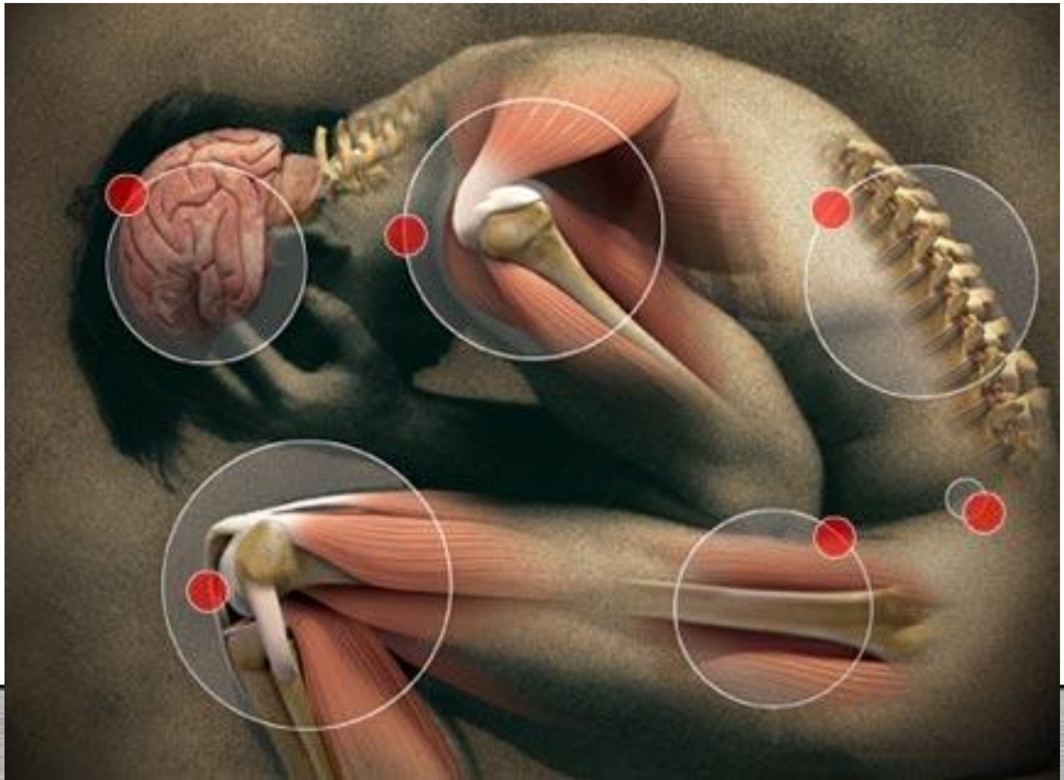
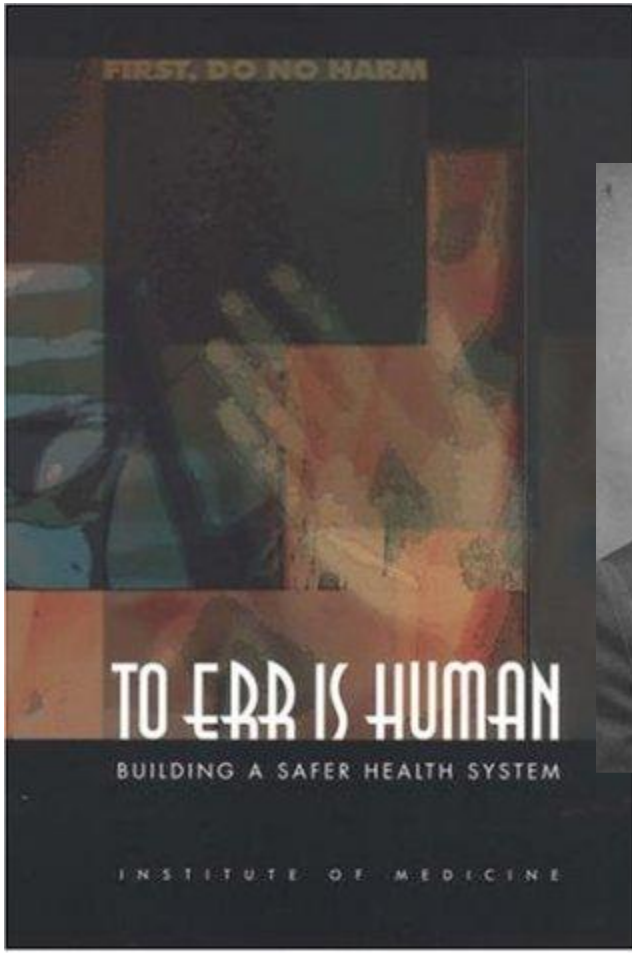
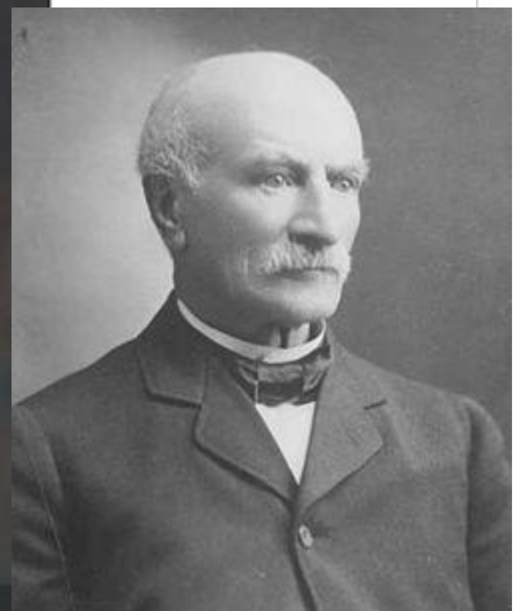
Errors Eliminate Profits

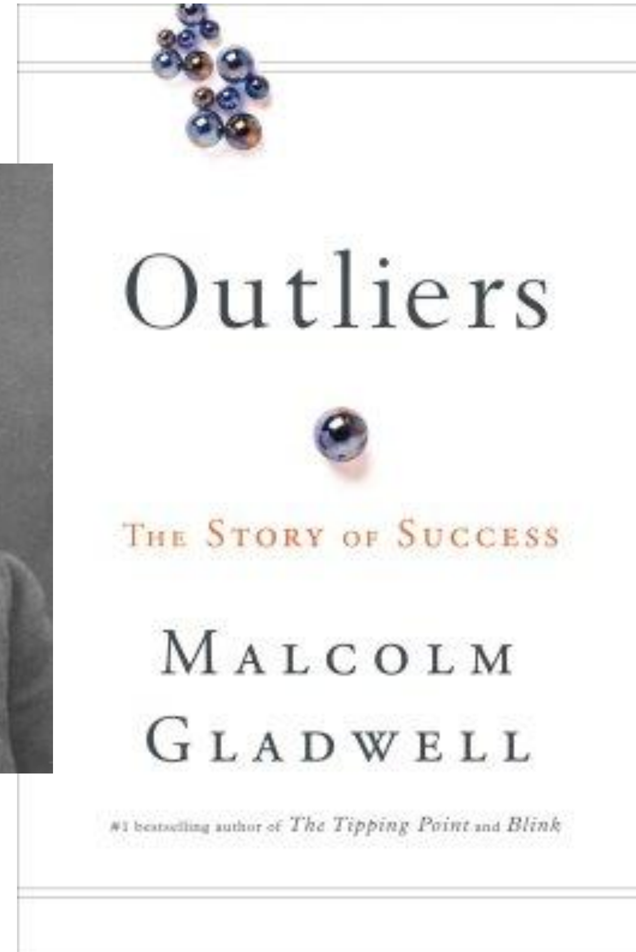
- **Minor Complication**
  - **Revisit <u>eliminates all profit</u> from the original surgery**
- **Major Complication**
  - **Revisit <u>costs 3X the profit</u> from the original surgery**



Creating Experts & Eliminating Errors







10,000 hours to become an expert - Gladwell

“There is no excuse for the surgeon to learn on the patient.” – William Mayo, 1927

Medical Education – Explosion of Information

- Medical procedures are becoming more numerous and more complex – medical knowledge has "hypertrophied" (Cooke, 2006)

- Training residents to a common level of knowledge and competence is already impossible (Satava, 2008)

"The Perfect Storm" (Murphy, 2007)

- Risk to patient health. (McDougall, 2007)
- Ethics of practicing on patients. (Satava, 2004; Murphy, 2007)
- Cost is a barrier to training. (Bridges, 1999)
- Insurance coverage of educational actions. (Satava, 2004)
- Working hour limits. (Satava, 2004)
- Availability of training opportunities. (Birden, 2007; Davis, 1999)
- Access to training. (Dunkin, 2007; Spitzer, 1997)
- Complexity of modern surgery. (McDougall, 2007)
- Volume of unique procedures. (Reznick & MacRae, 2006)
- Proficiency-based Medicine. (Murray, 2005)
- Quality of technology. (Murphy, 2007)
- Expectations around computer technologies. (Murphy, 2007)
- Acceptance of technology. (Ziv, 2003)
- Learning from Mistakes. (Ziv, 2005)

Objectives for Simulation in Education

- **Objective 1: Reduce Cost**
- **Objective 2: Increase Case Access**
- **Objective 3: Reduce Training Time**
- **Objective 4: Reduce Errors**

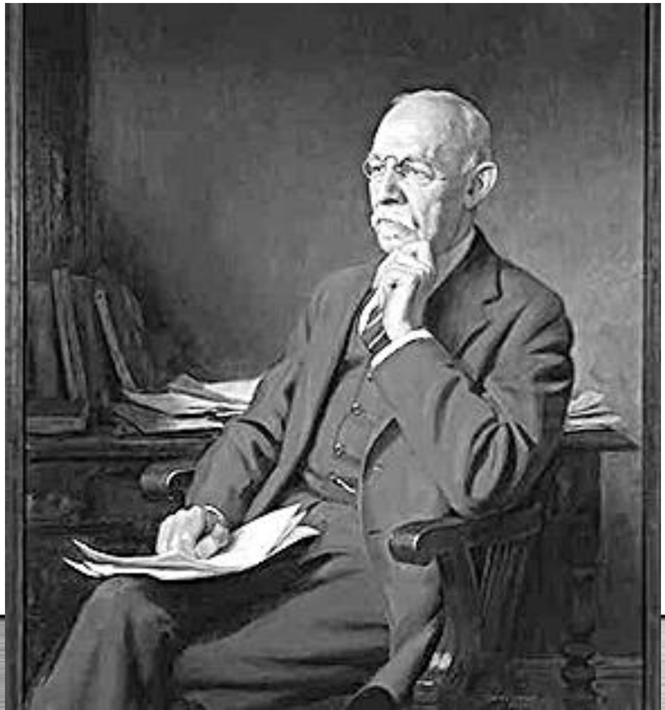
Similar Motivations in Military, Industrial, and Medical Training

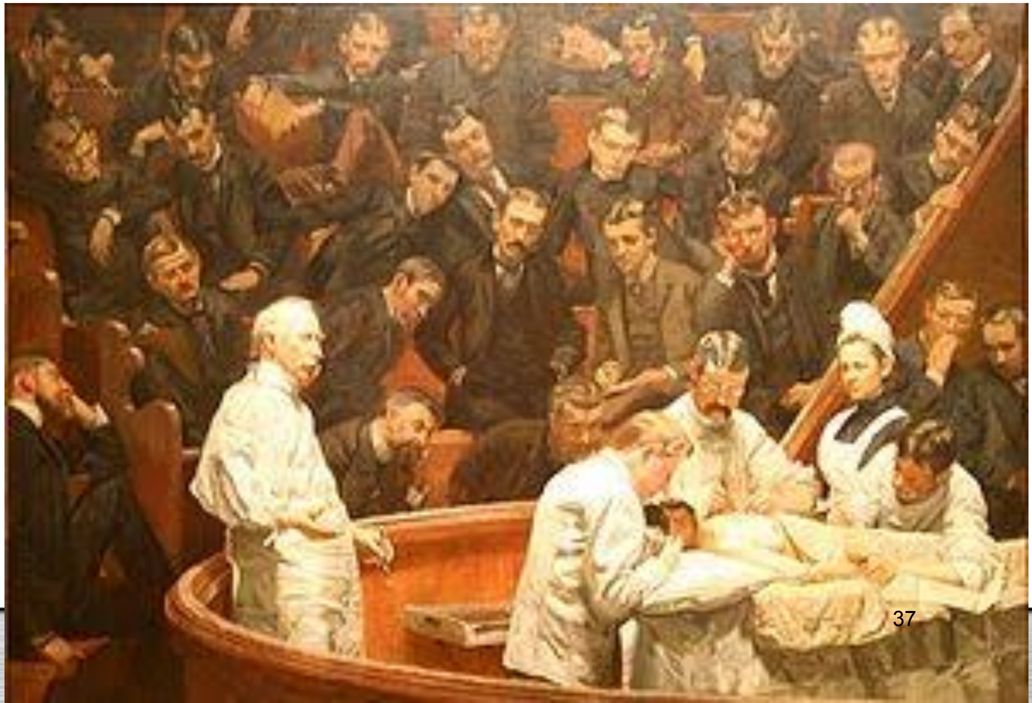
Objective 1: Reduced Cost

- Surgery as a teaching event consumes resources that could generate additional revenue. (Bridges & Diamond 1999)
  - 186 hours over a 4 year residency
  - Estimate OR costs at $257.40 per hour.
  - Adds $47,970 to the cost of a medical education.
- Updated: Adds $186,363 to $279,545 during four year residency
  - US OR is $1,500 per hour (Frost & Sullivan, 2004)
  - Swedish OR is $1,000 per hour (Hyltander, 2003)

Objective 2: Increased Access

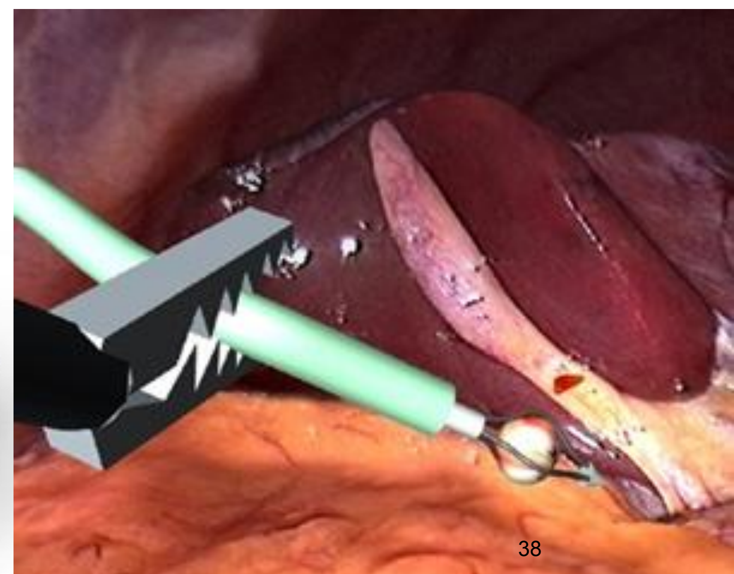
- Good laparoscopic skills cannot be developed by merely watching an expert.
- Laparoscopic proficiency is only realized after sufficient practice in the minimally invasive environment." (Pearson et al, 2002)
- Students trained in VR are <u>29% faster</u> at performing laparoscopic surgeries and make up to <u>five times fewer mistakes</u> (Enochsson et al, 2004; and Seymour, 2002)
- <u>Learning begins with "do one"</u> (Jordan et al, 2001; Gallagher et al, 2001b; Madan & Frantzides, 2007).





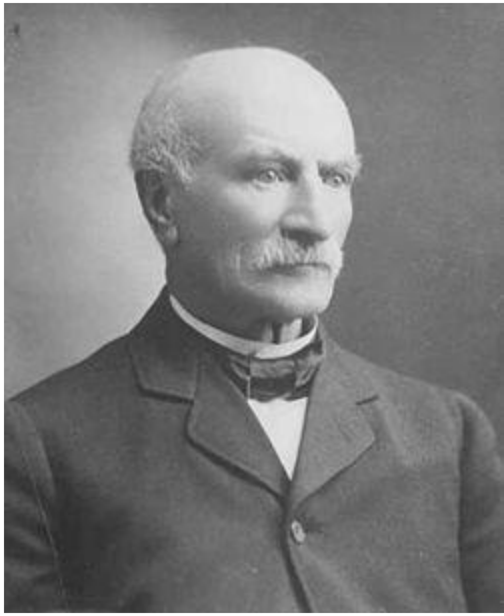
Objective 3: Reduced Time

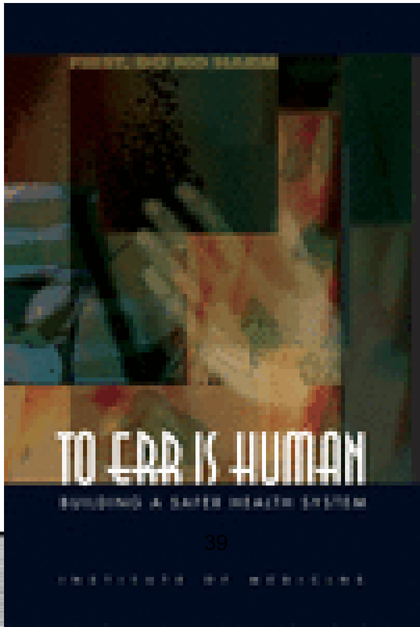
- Lap simulators <u>differentiate experienced from inexperienced</u> users based on their performance scores with the simulator (Adamsen et al, 2005)
- MIST-VR simulator could <u>determine which students will never achieve proficiency</u> and should be dropped from a training program (Gallagher et al, 2004)
- <u>Non-VR trained students are nine times more likely to fail</u> to make progress in their performance than those who use VR in their training (Seymour, 2002)



Objective 4: Reduced Errors

- Medical error is responsible for between 44,000 and 98,000 deaths per year (IOM, 1999).
- Laparoscopic surgery has an <u>error rate that is three times higher</u> than that of open surgery. Error rate has not been decreasing over an eight year period as surgeons become more experienced (Huang et al, 2005).
- In laparoscopy, <u>observation does little to convey the skills that must be mastered</u>. Only actual practice has been effective at this (Jordan et al, 2001; Gallagher et al, 2001b; Madan & Frantzides, 2007).
- Simulations can improve the performance of surgeons because they become familiar with the appearance of organs and tissue on a two dimensional computer monitor (Huang et al, 2005).





Misleading Assumptions in Traditional Education

- Assumption 1: Didactic Education is Effective
  - Though surgeons or residents may learn new information during educational lectures, they do not incorporate it into their practice. It has no impact on their actions in delivering medicine. (Davis et al 1995 & 1999; Weller et al 2005)

- Assumption 2: Sufficient Access to Faculty and Patients is Possible
  - Availability of faculty is a major limitation in medical education (Dunkin et al, 2007; Satava, 2008)
  - Many studies assume adequate access a priori (Gerson & Van Dam, 2003)

- Assumption 3: Practicing on Live Patients is Acceptable
  - Medical schools, faculty, and residents are finding new restrictions on the type and amount of training that can be conducted with a live patient (Murphy et al, 2007; Murray et al, 2005; Satava, 2004a; Ziv et al, 2005).

Training Technology Options

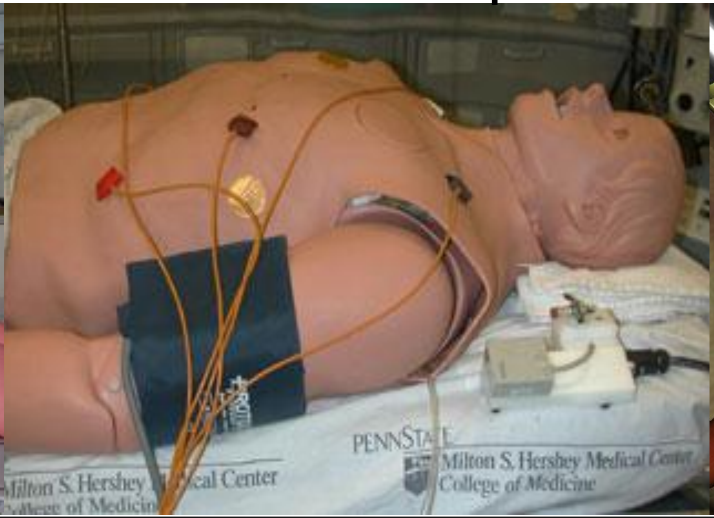
Human

Animal

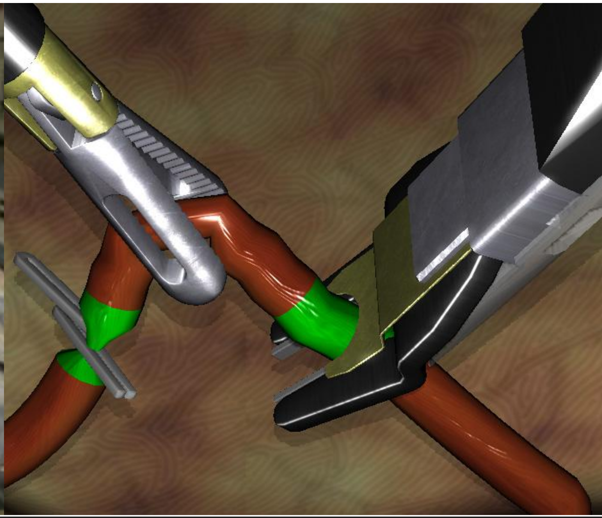
Box Trainer

Part Task

Mannequin



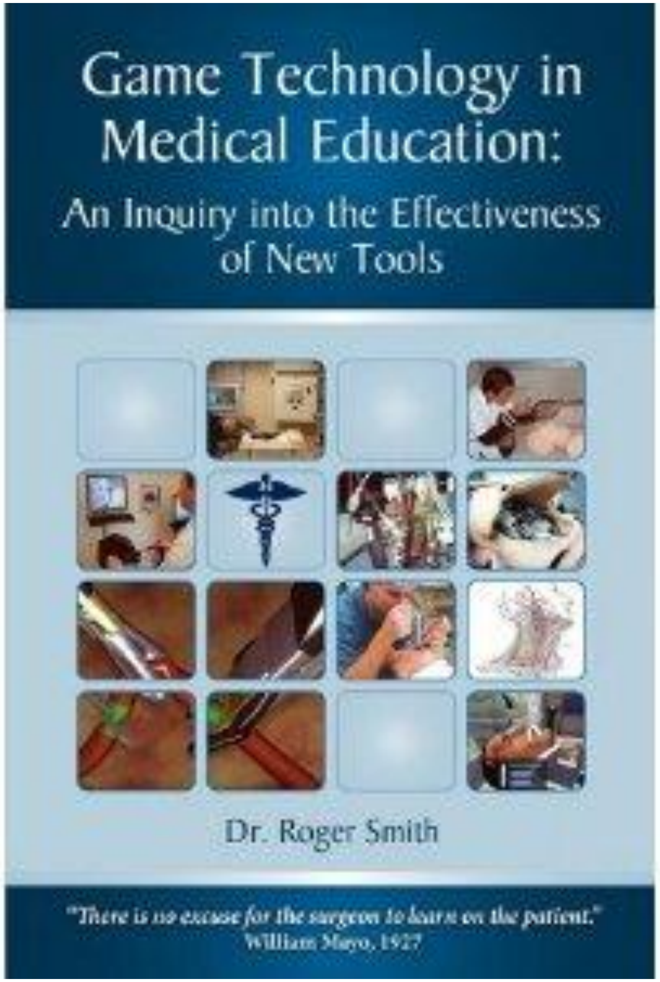
VR/Game Tech



Human	Animal	Box Trainer	Mannequin	Simulation	VR/Game
Learn on humans: Living patients, the newly dead, and cadavers	**Learn on animals:** Living and newly dead pigs, cats, and others	**Learn on organs in a box:** Human-shaped box contains organs, tissue, or test devices	**Learn on a physical replica:** A full-body device with synthetic skin, organs, and fluids	**Learn on an animated machine:** Includes computer, hydraulics, pneumatics, and electrical responses	**Learn on computer images:** Mathematical models, visual images, sounds, and some tactile feedback
Advantage Exact Replica, Existing OR	**Advantage** Similarities, Availability	**Advantage** Availability, Convenience, Human Shape	**Advantage** Human Shape, Logistics	**Advantage** Rich Experience, Multi-Function, Programmable	**Advantage** Rich Experience, Flexibility, Low Cost
Disadvantage Scarcity, Single Use, Ethical Issues	**Disadvantage** Anatomy, Single Use, Social Mores	**Disadvantage** Not Alive, Single Use, Animal Organs	**Disadvantage** Static, Lacks Realism	**Disadvantage** High Cost, Complexity	**Disadvantage** Screen-barrier, Non-tactile
Examples Cadavers Live Patients	**Examples** Porcine Labs	**Examples** MIC-Trainer	**Examples** CPR Annie	**Examples** Sim One HPS	**Examples** MIST-VR dV-Trainer

Complete Study

Smith, R. (2009). *Game Technology in Medical Education*. Modelbenders Press.



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Simulation & Surgical Training: Fundamentals of Robotic Surgery

Roger Smith, PhD

Chief Technology Officer

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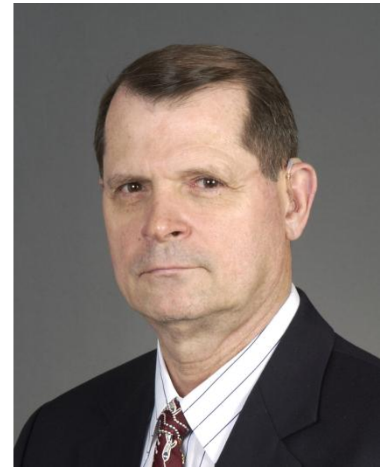
www.nicholsoncenter.com

Grants Leadership



PI's: Vipul Patel, MD & Roger Smith, PhD
Florida Hospital Nicholson Center

Source: US Department of Defense

PI: Richard Satava, MD
Minimally Invasive Robotics Assoc

Source: Intuitive Surgical Inc.

* This work was supported by an unrestricted educational grant through the Minimally Invasive Robotics Association from Intuitive Surgical Incorporated.

** This effort was also sponsored by the Department of the Army, Award Number W81XWH-11-2-0158 to the recipient Adventist Health System/Sunbelt, Inc., Florida Hospital Nicholson Center. "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office." The content of the information does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

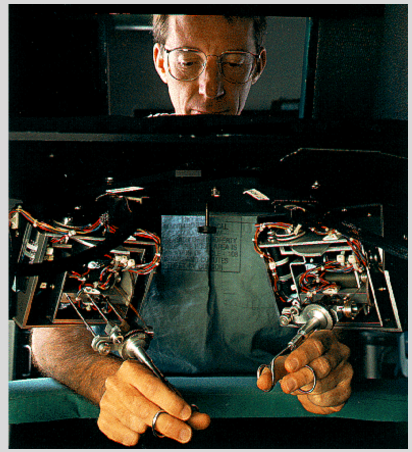
Congressional/DoD Research Project

Robotic Curriculum

Curriculum Development:
- Define Robotic Surgery outcomes
- Develop Robotic Surgery curriculum
- Develop specific training tasks

Curriculum Validation:
- Validate training tasks
- Identify testing measures
- Set passing criteria

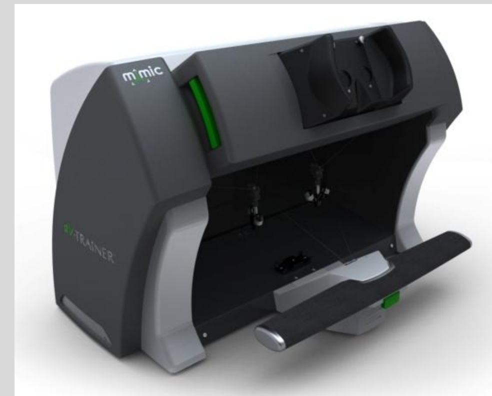
Telesurgery



Communication Latency:
- Map surgical movements to latency
- Redesign for latency tolerance
- Introduce instruments for safety
- Target city-pairs by latency

Automatic Surgery:
- Record movements in simulator
- Execute movements with robot
- Measure accuracy of outcome

Simulation



Surgical Rehearsal:
- Patient-specific rehearsal simulator
- Simulated patient physiology
- Measure impact on surgical perform

Military-use Validation:
- Identify military constraints
- Validate simulator for military-use
- Define deployable package

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Intuitive Surgical's Training Pathway

Surgeon and OR Team Pathway

Phase	Content	Trainer
I: Introduction to *da Vinci* Surgery ▼	Product Training ▼	Intuitive Surgical
II: Preparation and System Training ▼		
III: Post System Training ▼	Clinical Training ▼	Independent Surgeons & Societies/Academic Institutions
IV: Advanced Training ▼		
Beyond the Pathway	Continuing Clinical Education	Independent Surgeons & Societies/ Academic Institutions

- Phases I-II focus on product training, while phases III-IV focus on clinical training
- Beyond the pathway, skills are honed with continuing clinical education

FRS Mission Statement

Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

Note: The intent is to create a curriculum that is device-independent. This is admittedly difficult given the single approved surgical robot at this time. Therefore, significant attention is being paid to material that is device-flexible in anticipation of future robots.

Participating Organizations

- **American Association Gynecologic Laparoscopy (AAGL)+**
- American College of Surgeons (ACS)
- American Congress of OB-Gyn (ACOG)
- **American Urologic Association (AUA) +**
- American Academy of Orthopedic Surgeons (AAOA)
- American Assn of Thoracic Surgeons (AATS)
- American Assn of Colo-Rectal Surgeons (ASCRS)
- American Assn of Gynecologic Laparoscopists (AAGL)
- **Florida Hospital Nicholson Center***
- **U.S. Department of Defense (DoD)***
- U.S. Department of Veterans Health Affairs (VHA)
- **Minimally Invasive Robotic Association (MIRA)***
- Society for Robotic Surgery (SRS)
- **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) +**
- American Board of Surgery (ABS)
- Accreditation Council of Graduate Med Education (ACGME)
- Association of Surgical Educators (ASE)
- Residency Review Committee (RRC) – Surgery
- Royal College of Surgeons-Ireland (RCSI)
- Royal College of Surgeons-London (RCSL)

*** Funding Sources**
+ Executive Committee

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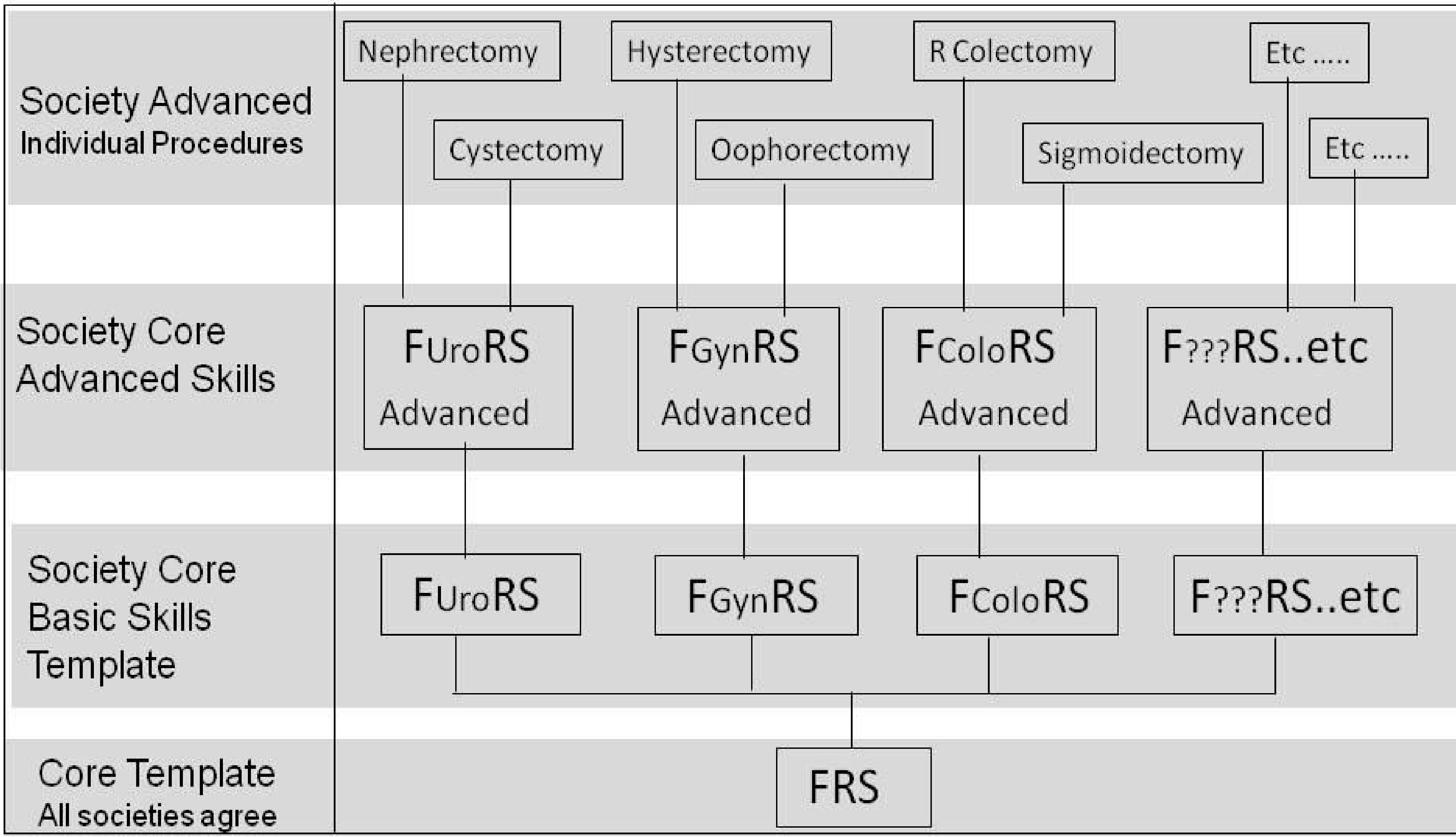
Development of Curriculum from common template

“Sweet* Tree”



* Adapted from Rob Sweet, MD, Professor of Urology, University Minnesota, 2010

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The Metrics Drives the Process

Curriculum Development

WHAT	Outcomes & Metrics	Curriculum Development	Simulator Development	Validation Studies	Implement: Survey Training Certification	Issue Certification
HOW	Consensus Conference	Standard Curriculum Template	Engineering Physical Simulator	Standard Validation Template	Current Procedures	Issue Mandates And Certificates
WHO	ABS SAGES ACS Specialty Societies	SAGES ACS Societies Academia	Industry with Academia Medical Input	ACS SAGES, Participating Societies	FLS SAGES/ACS	ABS certifier

Creator: Rick Satava, MD, Univ of Washington

Consensus Conference Process

1. Outcomes Measures (Dec 12-13, 2011)
2. Curriculum Outline (April 29-30, 2012)

2.5 Curriculum Development (Aug 17-18, 2012)

3. Validation Criteria (December, 2012)
4. Validation Studies
5. Transition to Objective Testing Organization (est. July 2013)

•Expert Discussion and Contributions
•Modified Delphi Voting Mechanism

#1 Outcomes Measures

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

Faculty Members: Outcomes Measures

• Arnold Advincula, MD	American Assoc of Gynecologic Laparoscopists & ACOG
• Rajesh Aggarwal, MD	Royal College of Surgeons - London
• Mehran Anvari, MD	Minimally Invasive Robotic Association (MIRA)
• John Armstrong, MD	USF Health, CAMLS (now Florida Surgeon General)
• Paul Neary, MD	Royal College of Surgeons - Ireland
• Wallace Judd, PhD	Authentic Testing Corp.
• Michael Koch, MD	American Board of Urology
• Kevin Kunkler, MD	US Army Medical Research & Materiel Command TATRC
• Vipul Patel, MD	Global Robotics Institute - Florida Hospital Celebration Health
• COL Robert Rush, MD	US Army Madigan Healthcare System
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• Danny Scott, MD	Society of American Gastro and Endoscopic Surgeons (SAGES)
• Mika Sinanan, MD	University of Washington
• Roger Smith, PhD	Florida Hospital Nicholson Center
• Dimitrios Stefanidis MD	Association for Surgical Education
• Chandru Sundaram, MD	American Urological Association
• Robert Sweet, MD	American Urological Association
• Edward Verrier, MD	Joint Council on Thoracic Surgery Education

Skills Definition (Sample)

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, (more)	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	3	6	33	3
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing.	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue, Stress and strain indentation and deformation	0	0	3	6	33	4

#2 Curriculum Development

Didactic & Cognitive	Psychomotor Skills	Team Training
Lecture-based	**Principle-based**	**Checklist-based**
Intro to Robotic System	Based on Physical Models (Virtual Models are Derivative)	#1: WHO Pre-Op
Pre-Operative Activity	3D Exam Tools	#2: Robotic Specific
Intra-Operative Activity	Use Tasks that have Evidence of Validity	#3: Undocking & Debriefing
Post-Operative Activity	Multiple Outcomes Measured per Exercise	#4 Crisis Scenarios
Each Activity includes: Goals, Conditions, Metrics, Errors, Standards	Cost Effective Solution	
	High Fidelity for Testing, Lower Fidelity for Training	
	IRR Requires Ease of Administration	

Faculty Members: Curriculum Develop

- Arnold Advincula
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- David Albala
- Richard Angelo
- James Borin
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- Arby Kahn
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- Rajesh Kumar
- Gyunsung Lee
- Raymond Leveillee
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- C.Y. Liu
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- Fred Loffer
- Guy Maddern
- Scott Magnuson
- Javier Magrina
- Michael Marohn
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- Amir Szold
- Raju Thomas
- Oscar Traynor
- Thomas Whalen
- Gregory Weinstein

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Testing Environments

Robot

Simulator

#3 Validation Conference

- Criteria
  - Validate the curriculum and passing criteria that will be used to grant certification
- Multi-Institutional Study
  - 10 independent sites
  - ACS AEI accredited
  - Faculty in at least 2 specialties

Florida Hospital Nicholson Center

Conclusions

- Objective curriculum in robotic surgery is needed for certification
- Development of such a curriculum is underway by a multi-specialty working group of experienced surgeons
- Florida Hospital is actively supporting this effort with surgical experts and grant funding

Panel: Examining and Measuring Training Effectiveness

Roger Smith, Florida Hospital

Troy Reihsen, University of Minnesota

Matthew Lineberry, Naval Air Warfare Center

FLORIDA HOSPITAL
NICHOLSON CENTER

Fundamentals of Robotic Surgery: Curriculum and Certification

Roger Smith, PhD

Chief Technology Officer

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www.nicholsoncenter.com

Robotic and Telesurgery Research Project

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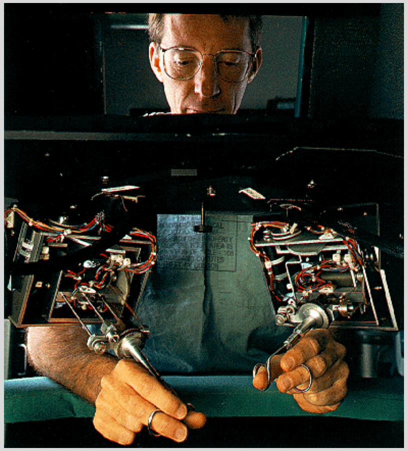

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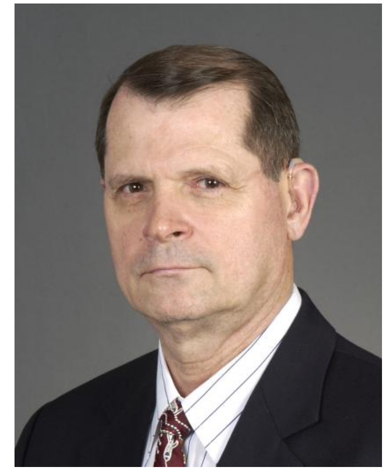
Grants Funding Work





PI: Roger Smith, PhD & Vipul Patel, MD
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Download Reports, Papers, and Presentations

http://www.simulationfirst.com/frs

Thank You!

Using Simulators to Measure Communication Latency Effects in Robotic Telesurgery

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University of Minnesota Medical School
Minneapolis, MN
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ABSTRACT

Robotic surgical technology was originally developed by the US Army and DARPA as a tool to enable telesurgery at a distance. The Intuitive da Vinci system now provides a robotic surgical tool in a traditional operating room. But research continues into the extension of this capability to patients that are remote from the surgeon's location. In this paper we describe the interim results of experiments into the effects of communication latency in the safe execution of robotic telesurgeries. These experiments were carried out with the Mimic dV-Trainer, a simulator of the da Vinci robot, which was configured to insert defined levels of latency into the visual and command data streams between a surgeon and the operating field. Subjects were asked to perform four basic robotic surgical exercises. They were allowed to rehearse these in a zero latency environment and with a randomly assigned latency between 100ms and 1,000ms. Then each subject performed each exercise for measurement and analysis in our research.

This experiment measured the degradation of human surgical performance across a range of latency conditions. This paper reports on the comparison of the level of experience of the surgeons with their performance in a latency-effected environment. The data collected thus far refutes our hypothesis that more experienced surgeons would be more successful at managing the effects of latency and would perform better than those with less experience. Subjects in our experiment show no correlation between experience and successful performance under latency. The ability to manage latency in tele-operations may be shared between remote surgery and the control of a remotely piloted UAV's and UGV's. The results of our experiments may suggest that experience as a traditional pilot does not necessarily contribute to useful skills in flying UAV's or driving UGV's when latency is present.

ABOUT THE AUTHORS

Roger Smith, PhD, is an expert in the development of simulation devices and training programs. He has spent 25 years creating leading edge simulators for the Department of Defense and Intelligence agencies, as well as accredited methods for training with these devices. He is currently the Chief Technology Officer for the Florida Hospital Nicholson Center where he is responsible for establishing the technology strategy and leading technology implementation through the development of alliances with industry, the military, academic institutions, physician networks and governing medical associations. This includes identifying, executing and managing industry, military and federally funded simulation, modeling and training projects. He has served as the CTO for the U.S. Army PEO for Simulation, Training and Instrumentation (PEO-STRI); VP and CTO for training systems at Titan Corp; and Vice President of Technology at BTG Inc. He holds a Ph.D. in Computer Science, a Doctorate in Management, and an M.S. in Statistics. He has published 3 professional textbooks on simulation, 11 book chapters, and over 100 journal and conference papers. His most recent book is *Innovation for Innovators: Leadership in a Changing World.* He has served on the editorial boards of *Transactions on Modeling and Computer Simulation* and *Research Technology Management*.

Sanket Chauhan, MD, is a Robotic Urology Fellow at the University of Minnesota Medical School. Prior to this he was with the Florida Hospital, Global Robotics Institute and an instructor of Urology at the University of Central Florida's College of Medicine. Dr. Chauhan's research interests include developing new technologies for the future of surgery, telesurgery, surgical education, advanced surgical technologies, surgical simulation and the use of virtual reality and augmented reality in surgery. He has published more than 25 papers in peer reviewed journals and has authored 3 book chapters. Dr Chauhan is committed to surgical education using next generation VR based simulators. He is a member of the program committee for International Association for Science and Technology for Development (IASTED) Robotics and Control conference in 2010, and the World Robotic Surgery Symposium.

Using Simulators to Measure Communication Latency Effects in Robotic Telesurgery

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BACKGROUND

Robotic surgery has been the topic of science fiction and scientific research for decades. As early as 1942, Robert A. Heinlein published the story “Waldo” in *Astounding Science Fiction*. He described the use of gloves and a harness to allow Waldo Jones to control mechanical arms of any size from large industrial and construction equipment to miniature tools for electronic and surgical work. The Industrial Revolution gave us many of the tools needed to extend the capabilities of the human body, but the Information Age gave us the computerized control systems necessary to effectively manipulate these devices. Surgical robots are a marriage of mechanical, electrical, optical, and software systems that can empower a human surgeon to peer into a patient’s body with magnified stereo vision, probe the internal organs, and perform effective surgery without fully opening the patient’s body.

In 1985, the PUMA 560 was used to accurately place a needle for a brain biopsy using CT guidance (Kwoh et al, 1988). In 1988, the PROBOT at Imperial College London, was used to perform prostate surgery. In 1992, Integrated Surgical Systems introduced ROBODOC to mill precise fittings in the femur for hip replacement. Intuitive Surgical leveraged the research work of the Defense Advanced Research Projects Agency (DARPA) and used those technologies to create the da Vinci Surgical System which they introduced in 1997. Computer Motion followed a similar path and fielded the AESOP and ZEUS robotic systems (Figure 1), which were later acquired by Intuitive Surgical (Satava, 1998; FDA, 2005).

Figure 1. ZEUS Surgical Research Robot

Intuitive Surgical’s da Vinci robot is currently the only FDA approved device for robotic surgery on human patients. This system senses the surgeon’s hand movements and translates them into scaled-down micro-movements to manipulate tiny instruments inside the body. It also detects and filters out any tremors in the hand movements, so that they are not expressed robotically. The camera used in the system provides a true stereoscopic picture transmitted to and viewed through a surgeon's console (Figure 2).

These devices opened the door for the realization of surgery-at-a-distance, a.k.a. telesurgery, in which a surgeon is able to extend his reach and perform surgical procedures at a significant distance from the patient. This capability has been demonstrated under unique conditions by multiple experiments (Himpens, 1998; Janetschek, 1998; Fabrizio, 2000; Sterbis, 2007). Our research project at the Florida Hospital Nicholson Center is demonstrating the maturity of the existing telecommunication infrastructure within a hospital system to support daily, on-demand telesurgery right now. Our experiments are based on the da Vinci surgical robot (Intuitive Surgical, Inc.) and the dV-Trainer simulator (Mimic Technologies, Inc.).

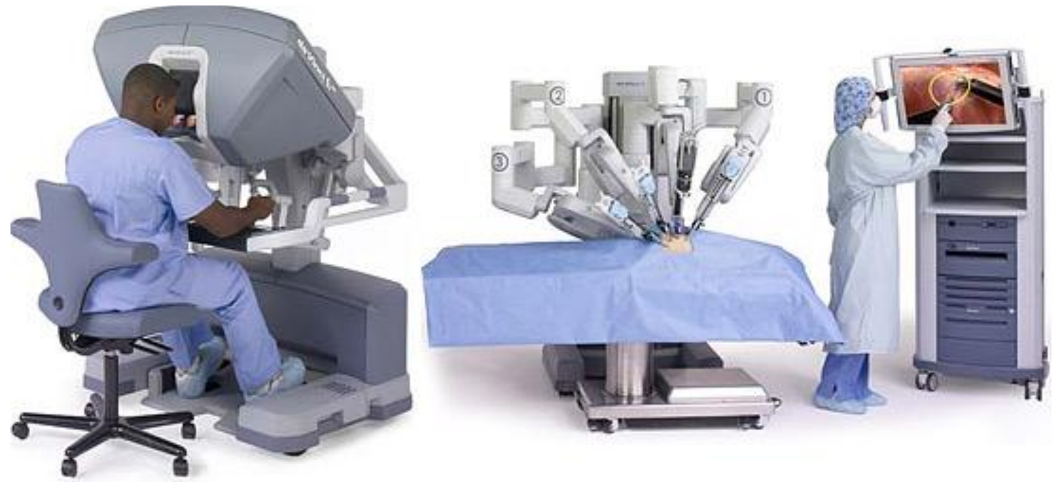


Figure 2. da Vinci Surgical Robot (Intuitive Surgical, Inc.)

METHODS

We explore the effects of communication latency on surgeon performance. This latency effect is created using the dV-Trainer simulator (Figure 3) of the da Vinci surgical robot (Hung, 2011; Kennedy 2009). The simulator allows the insertion of specific levels of controlled latency so that the user's physical movements are not manifest by the simulated instruments until after the defined latency period has elapsed.

Figure 3. dV-Trainer Simulator (Mimic Technologies, Inc.)

During actual telesurgery, the messages sent between the surgeon's machine and the remote patient station will be delayed due to the speed of light and the message routing that occurs on the internet. Determining how much latency can be safely tolerated in surgery is an important question (Anvari, 2005 and 2007). This experiment hypothesizes that there are two distinct thresholds of performance under increasing latency. The first is the level of latency at which a surgeon can first detect that his or her movements are being affected by the communication link. Any communication latency lower than this level is imperceptible and potentially non-invasive to the surgical procedure. Hence, if such levels can be achieved in the real world, then telesurgery may be safe for human surgery right now. The second level is the point at which the surgeon's performance is degraded to the point that the surgery cannot be performed safely (Marescaux, 2002; Lum, 2009). This level is identified through both simulator measured performance and the expert opinion of the surgeon. Between the first and second thresholds, a surgeon may be able to successfully control the effects of latency and perform a safe and successful procedure. Beyond the second threshold, telesurgery would be considered unsafe with the available equipment (Figure 4).

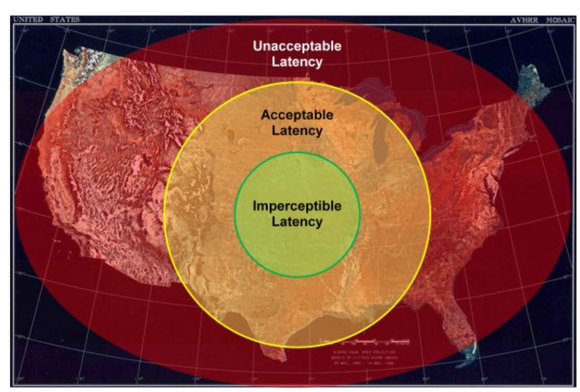
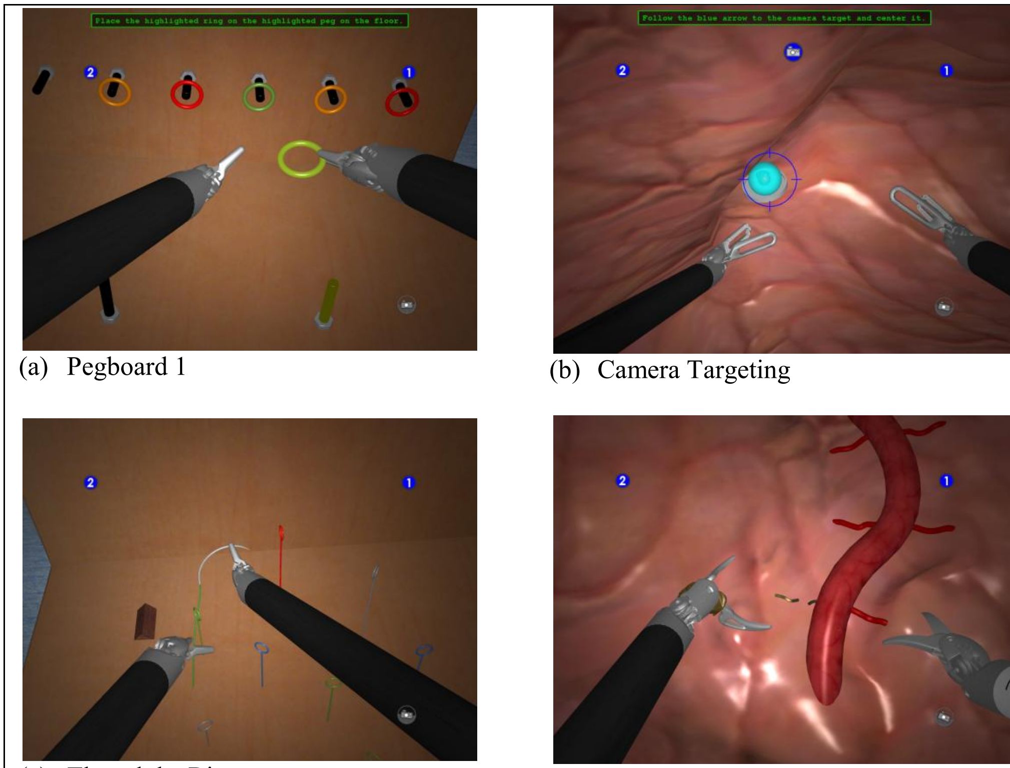


Figure 4. Conceptual Diagram of Communication Latency Thresholds.



(a) Pegboard 1 (b) Camera Targeting

(c) Thread the Rings (d) Energy Dissection

Figure 5. Simulated Surgical Skills Tasks

We further hypothesize that more experienced surgeons will be more successful at managing the effects of latency and would be the best practitioners for this extension of robotic surgery. If this hypothesis is correct, then surgeons with more experience should achieve higher scores and shorter completion times in the simulation experiment that we are performing. This paper reports on the analysis of this specific question comparing surgeon experience to the ability to successfully manage the effects of latency.

In this experiment, subjects performed the four simulated surgical skills exercises shown in Figure 5. These represent many of the core skills that are required in robotic surgery. Each subject performed each exercise three times. First, the subject was given an opportunity to perform the task without any imposed latency. This baseline insured that they were able to successfully operate the controls under normal conditions. Second, they were allowed to perform each of the four exercises at their randomly assigned latency level. These repetitions provided the learning necessary to achieve a sustained level of proficiency within a latent environment (Rayman et al 2006). Finally, each subject performed all four exercises at the same randomly assigned latency level and their performance was measured for analysis in the study.

A single, constant latency level between 100 milliseconds (ms) and 1,000ms at increments of 100ms was randomly assigned to each subject (e.g. 100ms, 200ms, 300ms. 400ms, etc.). A proctor was available to instruct subjects in the use of the equipment and to guide them through the curriculum of the protocol. However, this proctor was not allowed to give suggestions on performance of the exercises or to tell the subject the specific level of latency that they were experiencing.

Data Collection

Experimental data was collected by the simulator software and manually via questionnaires. Research proctors administered a Pre-Test questionnaire on the level of surgical experience and related activities of the subject. All personal and performance data was anonymized to insure that the identity of the subject could not be linked to the data that was collected. The proctors also administered a Post-Test questionnaire at the conclusion of each of the skills exercises during the final performance stage. The simulator software automatically collected multiple measures of the

subject's performance. This provided data for all subjects at zero latency, during their familiarization stage with latency, and during the final stage which is the focus of the analysis. This data will allow us to perform multiple analyses of the skills of robotic surgeons both with and without communication latency, which will be published in future papers.

Pre-Test Questionnaire

The Pre-Test questionnaire identified multiple items of demographic, experience, and practice data on the subjects. These included: age, gender, dominant hand, surgical status, years of surgical experience, years of laparoscopic experience, years of robotic experience, number of weekly procedures in laparoscopy and robotics, and experience with laparoscopic and robotic simulators, as well as with video games and musical instruments. Additional questions captured their opinion on the use of simulation in surgical education and certification.

This data was then matched to the data from their performance in the simulator.

Simulator Performance

During the experiment, the simulator itself collected a number of data points on each subject's performance. These included: time to complete, overall score, total hand motion in centimeters, master working space, number of instrument collisions, number of items dropped, excessive instrument force, distance instruments out of view, incorrect use of electrical energy, simulated blood loss, and number of broken blood vessels.

Post-Test Questionnaire

As the subjects completed their final repetition of each of the four skills exercises, the proctor administered a post-test questionnaire which asked the subject for their opinion on the stress induced by the simulation with latency. This included measures of the mental and physical demands of the task, the pace of the task, their opinion on their level of success, the amount of effort expended, the level of mental discouragement experienced, and their perceived complexity of the exercise.

RESULTS

This paper reports on the analysis of data from the first 54 subjects in the study. Of the 54 subjects who began the experiment, several were unable to complete all of the tasks due to the limited amount of time that they could devote to the experiment. Others found the experiment too taxing and elected to terminate their participation before completion. As a result, we collected complete data sets without latency on 42 subjects and complete data with latency on only 21 of those subjects.

This data was analyzed to determine the level of correlation between the subjects' experience and their performance both with and without latency. For the non-latency sample size of 42 and $\alpha=0.05$, the Pearson Product Moment Correlation (PPMC) value is 0.304. This means that for a correlation coefficient of two variables in this size of sample to be significant, it must be larger than the PPMC value.

Table 1. Correlation Coefficients without Latency

Exercise	Overall Score	Time Complete
Pegboard 1	0.141	-0.110
Camera Targeting	0.201	-0.173
Thread the Rings	0.156	-0.225
Energy Dissection	0.267	-0.217

In an environment without any latency imposed we found a positive correlation between years of robotic experience and overall performance score, as well as a negative correlation between experience and the total time to complete the exercise (Table 1). Both of these indicate that more experience leads to better performance in the simulator. Though this correlation is consistently supportive that surgeons with more experience perform non-latency exercises better than those with less experience, the degree of this correlation is not large enough to be statistically significant for this sample size.

When latency is added, a simple correlation coefficient is not sufficient for analyzing the effect of robotic experience on performance. Each subject received a randomly assigned latency, of which there were 10 possibilities. Within the current sample, we have between 0 and 5 subject data points at each latency level. Therefore, under latency, we examine the data by visual examination of a multiline scatter plot.

Scatterplots can illustrate the linear relationship between two variables in the model. Without latency, a relationship can be seen for both overall performance score and time to complete the exercise (Figures 6 & 7). However, when latency is present, the plots show that there is not a relationship between the two variables for the subjects tested (Figures 8 & 9).

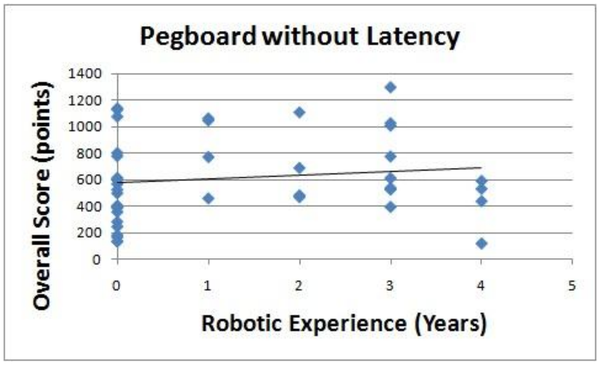


Figure 6. Correlation between Robotic Experience and Overall Score for the Peg Board exercise without communication latency.

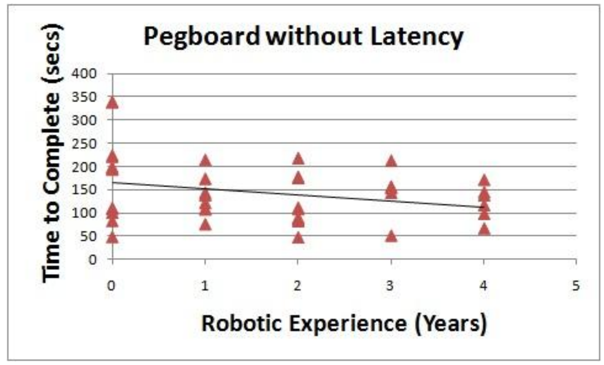


Figure 7. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise without communication latency.

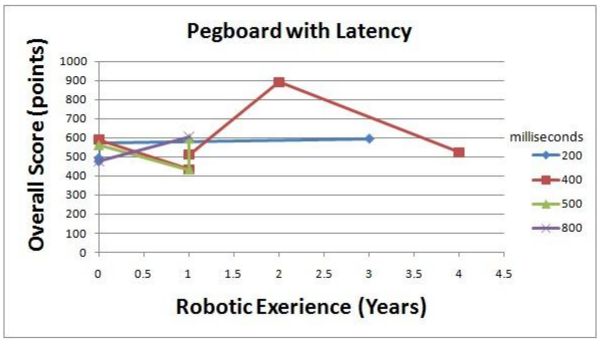


Figure 8. Correlation between Robotic Experience and Overall Score for the Peg Board exercise with various communication latencies.

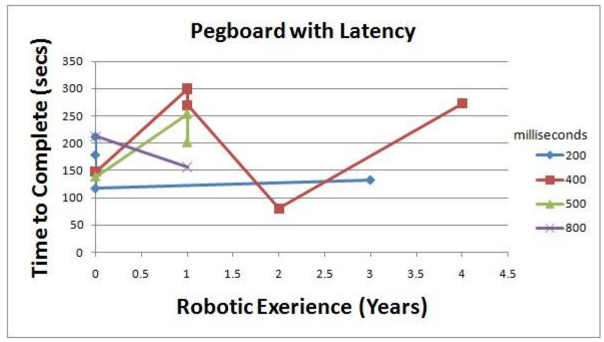


Figure 9. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise with various communication latencies.

The data suggests that surgeons who have more experience in robotic surgery are not better equipped to self-manage the challenges presented by communication latency in telesurgery. Subjects with little experience are as likely to successfully manage latency as are surgeons with more experience.

This same trend holds when comparing independent variables like total surgical experience and laparoscopic experience to the scores achieved in the simulator with latency.

CONCLUSIONS

The lack of correlation between experience and telesurgical performance under latency refutes our original hypothesis that a more experienced surgeon would more successfully manage the effects of latency. This negative finding has led to speculation on the cause of these results. Several may be possible, but each will require additional experimentation. First, experienced surgeons may be very talented, but fixed, in their methods of performing surgery. This may lead them to perform poorly under latency because it is difficult for them to modify their behaviors, where inexperienced surgeons are less ingrained and more adaptable to the situation. Second, since the simulator is a computer-generated virtual environment, it is possible that surgeons who have more experience in simulators, virtual worlds, and computer games may have developed a proficiency for solving problems in this kind of environment. They may also have experienced latency in those environments and developed techniques for compensating for it. Third, the ability to manage latency may be related to the physical and biological wiring of an individual. This could be a similar phenomenon to the tendency for some people to experience simulator sickness, while others do not suffer from it. These speculations are worthy of further investigation.

The objective of this analysis was to identify the degree to which a surgeon can compensate for the effects of latency that are present in a telesurgery environment. The long-term goal is to identify the thresholds where safe and successful surgery can be performed. Our findings at this point refute our hypothesis that more experienced surgeons would be able to manage latency more successfully. In the data collected there is no correlation between robotic experience and the ability

to achieve a higher score in the simulator when latency is inserted into the procedure.

These results may inform research on remote teleoperation in other environments, such as the control of UAV's and UGV's. Experienced pilots and vehicle drivers may not be better equipped to manage the effects of latency than pilots/drivers with less experience. Other factors may be more important in predicting a person's ability to tele-operate a remote system successfully. The similarity between remote surgery and remote vehicle operation is speculative and would require specific research experiments with those systems to verify.

ACKNOWLEDGEMENTS

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Robotic & Telesurgery Research Using Simulation

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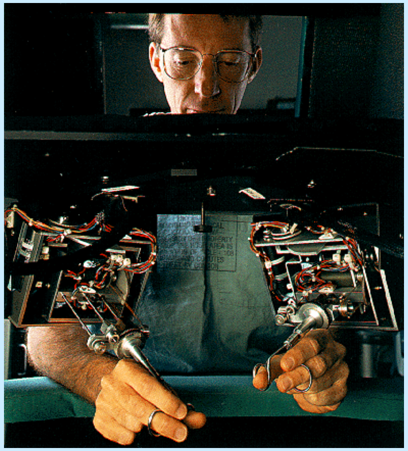
Robotic and Telesurgery Research using Simulation

Telesurgery



Comms Latency:
- Modify surgical procedures
- Safe Telesurgery at 500ms
- Match to City-Pairs

Automatic Surgery:
- Record Surgery in Simulator
- Execute with Unmanned Robot
- Identify Control Variables

Simulation

Surgical Rehearsal:
- Dynamic Organ Model in Sim
- Patient-specific Rehearsal
- Improve Surgeon Performance

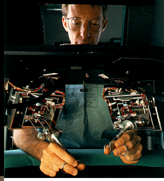
Military-use Validation:
- Simulator of Robotic Surgery
- Retain Skills in Theater
- Define Deployable Package

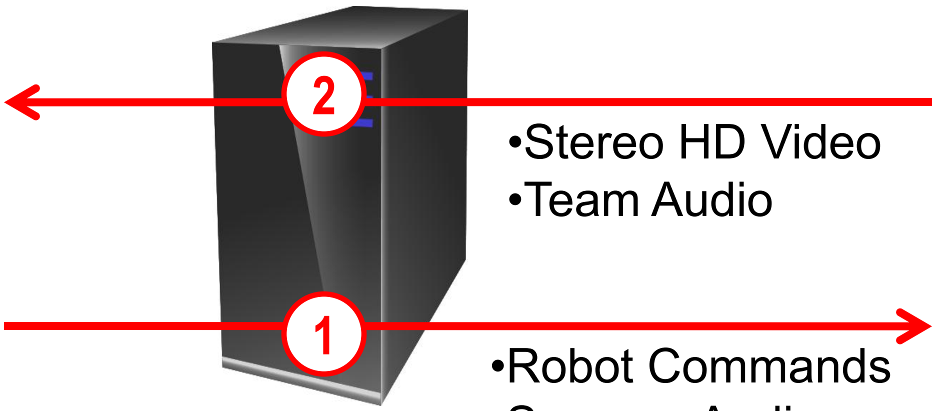
Robotic Curriculum

Consensus Conferences:
- Define Certification Criteria
- Develop Curriculum
- Develop Training Tasks

Curriculum Validation:
- Validate the Program
- Identify Testing Measures
- Set Passing Criteria

Telesurgery: Communication Latency



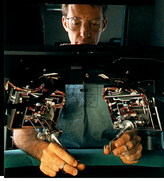


•Stereo HD Video
•Team Audio

•Robot Commands
•Surgeon Audio

Comm Latency = 1 + 2

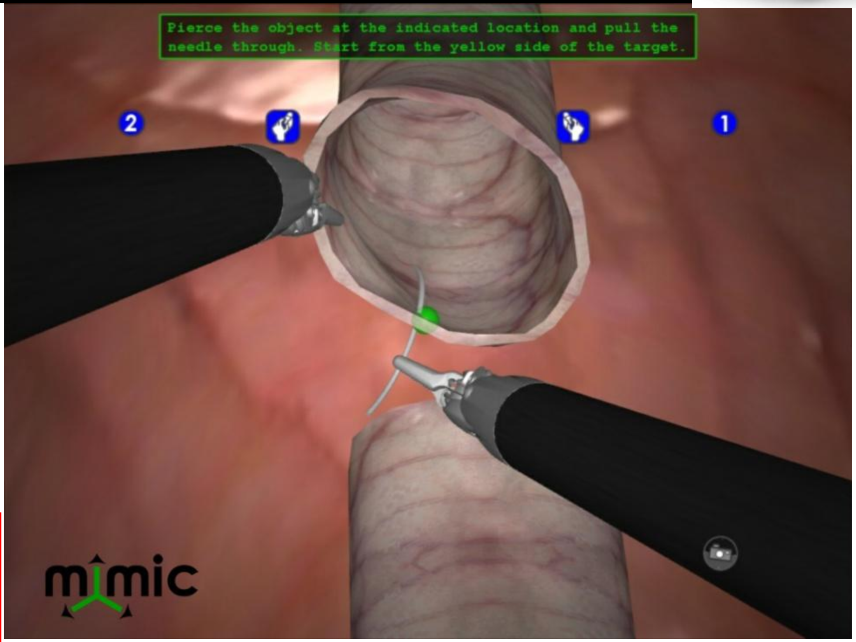
Telesurgery: Simulated Latency



da Vinci Skills Simulator

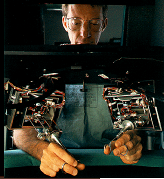
Mimic dV-Trainer

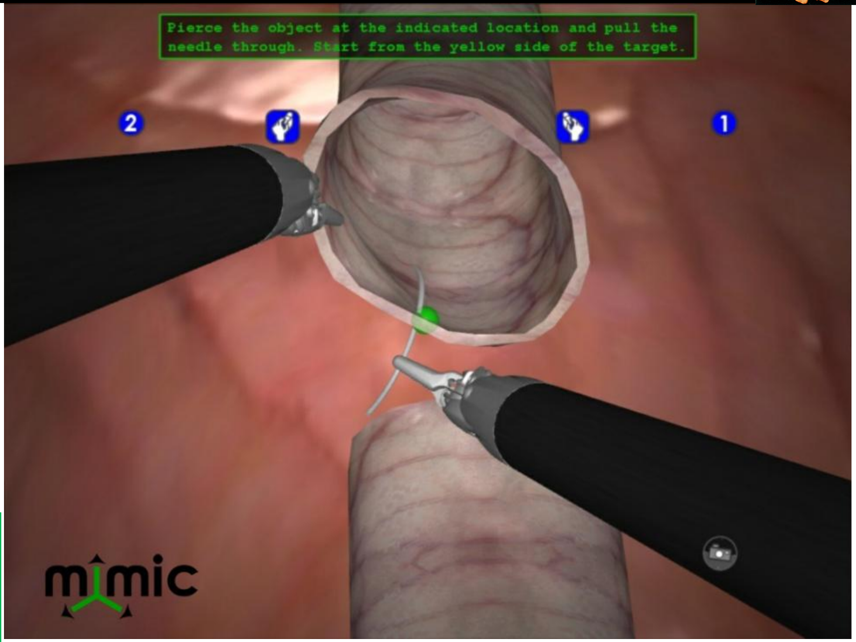
Simulation: Surgical Rehearsal



Skill
Trans

Telesurgery: Automatic Surgery





Data Trans

Industry Perspective

- **Simulation as a Research Lab**
  - Simulated environments are a viable and affordable research environment within which to conduct experiments.
- **Simulation for Rehearsal**
  - Simulation is a tool for real-time preparation for surgery.
- **Simulation for Education**
  - Redesigning GME surgical courses to include simulators along with classroom and laboratory components.

Robotic Surgery and Surgical Simulation

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- Leading research in exploration of telesurgery and applying simulation devices to surgical education
- CTO for U.S. Army Simulation, Training and Instrumentation (PEO STRI)
- CTO and Vice President at Titan Systems Inc.
- Research Scientist for Texas A&M University
- Serves as a Graduate Faculty Scholar at the University of Central Florida
- Visiting Lecturer at Georgia Institute of Technology
- Faculty at the Florida Hospital College of Health Sciences

- Published 5 Books (Chapter contributions to 10 books)
- 150 technical and management papers

- B.S. in Applied Mathematics
- M.S. in Statistics
- Master's and Doctorate in Business Administration
- Ph.D. in Computer Science.

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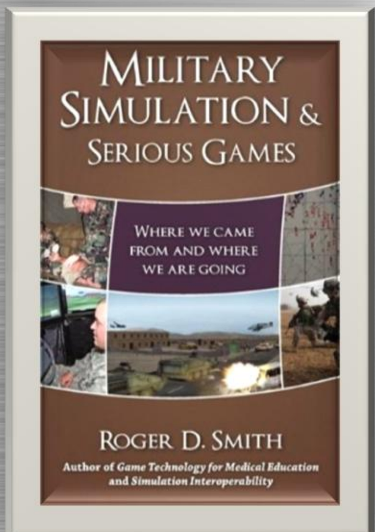
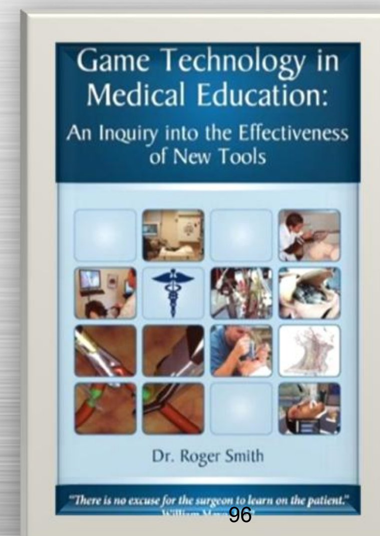


- Technical, Social and Economic importance of simulation and gaming
- Focus on techniques, tools and technologies
- Historical summary and future possibilities
- Explores and contrasts Military and Commercial gaming evolutions

- The traditional Halstedian apprenticeship model of 'see one, do one, teach one' is no longer adequate to train surgeons, since good laparoscopic skills cannot be developed by merely watching an expert." - A. Pearson, M.D.
- "There is no excuse for the surgeon to learn on the patient." - William Mayo, 1927
- Dr. Smith's Book proposes 4 hypotheses:
  1. Virtual Reality and gaming can reduce costs for surgical training
  2. VR and gaming can improve repetitive practice to assess patient symptoms
  3. VR and game training environments can reduce training times (for equal skill)
  4. VR and gaming can reduce medical errors



Florida Hospital

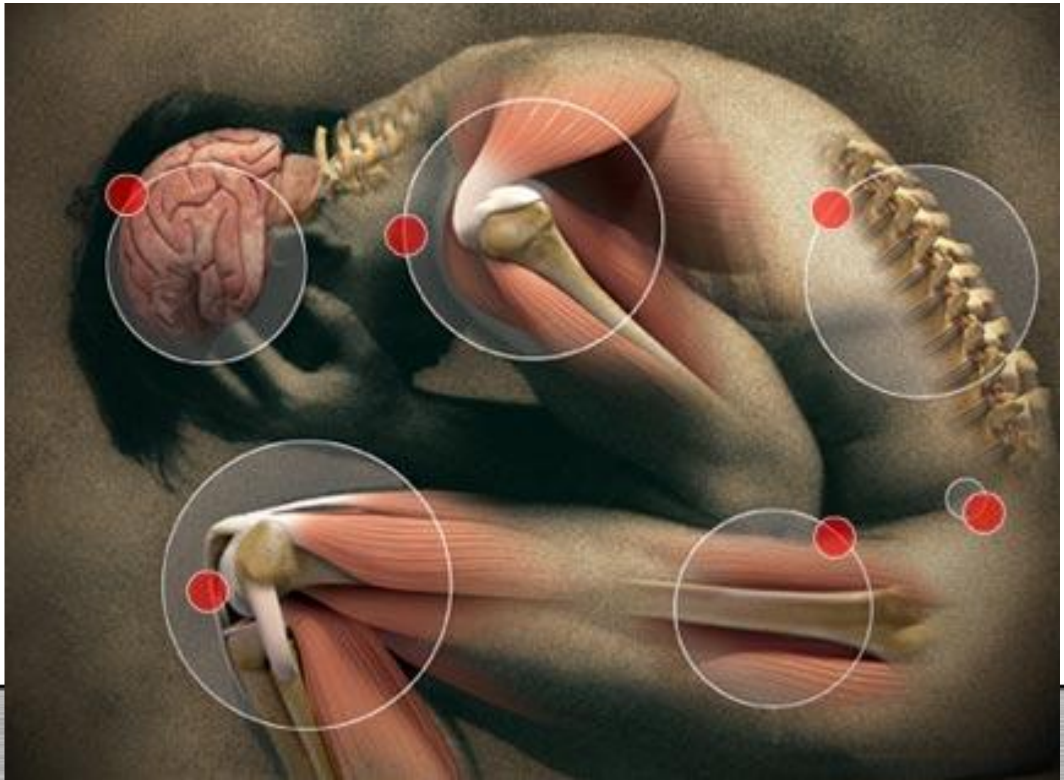
- 8 Campus Hospital System in Orlando, Florida
- 34 Regional Campuses across Florida
- 2,188 beds
- Largest provider of healthcare in Florida
- Largest by some measures in the entire United States

Nicholson Center

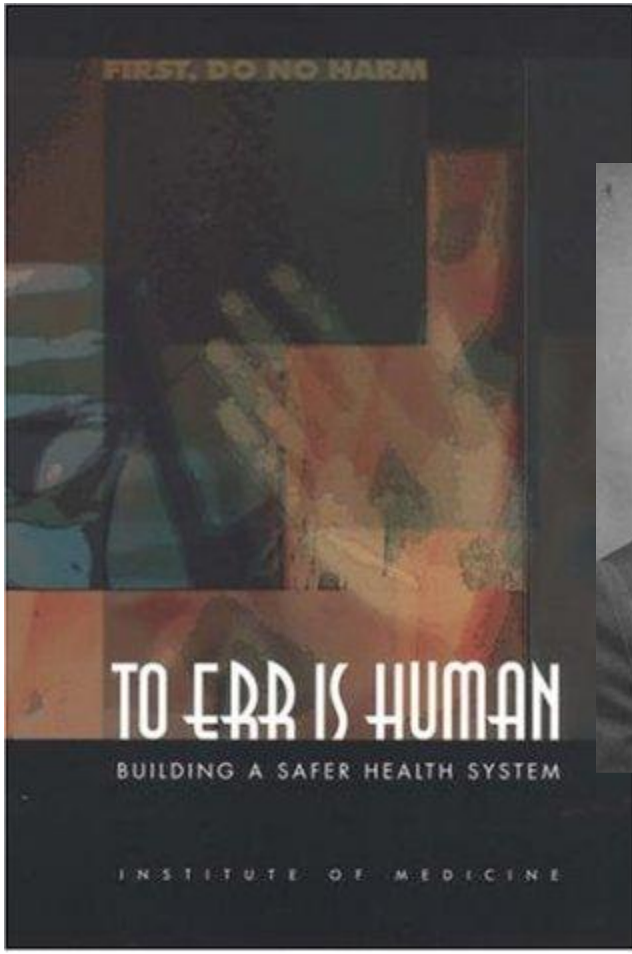
- **Surgical Education**
  - Robotic Surgery
  - Laparoscopic Techniques
  - Orthopedic Equipment
- **Surgical Research**
  - Robotic & Telesurgery
  - Surgical Education
  - Automatic Surgery

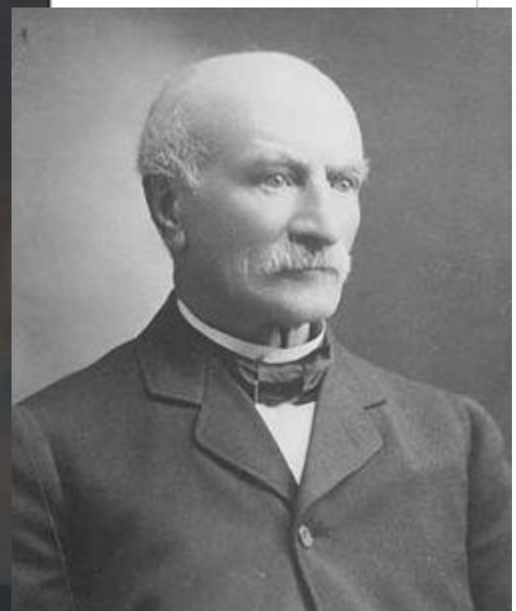
Errors Eliminate Profits

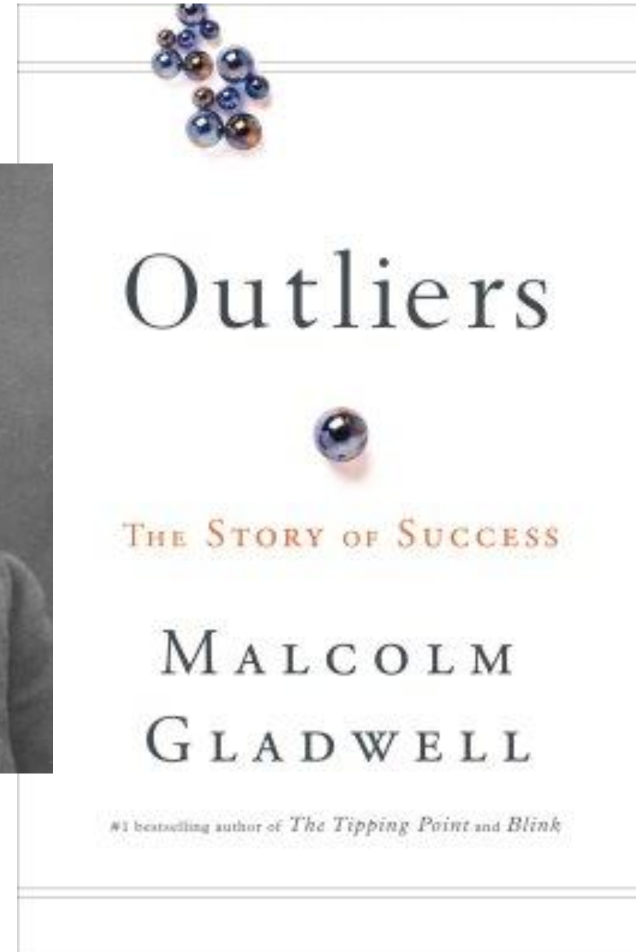
- **Minor Complication**
  - **Revisit <u>eliminates all profit</u> from the original surgery**
- **Major Complication**
  - **Revisit <u>costs 3X the profit</u> from the original surgery**



Creating Experts & Eliminating Errors







10,000 hours to become an expert - Gladwell

"There is no excuse for the surgeon to learn on the patient." – William Mayo, 1927

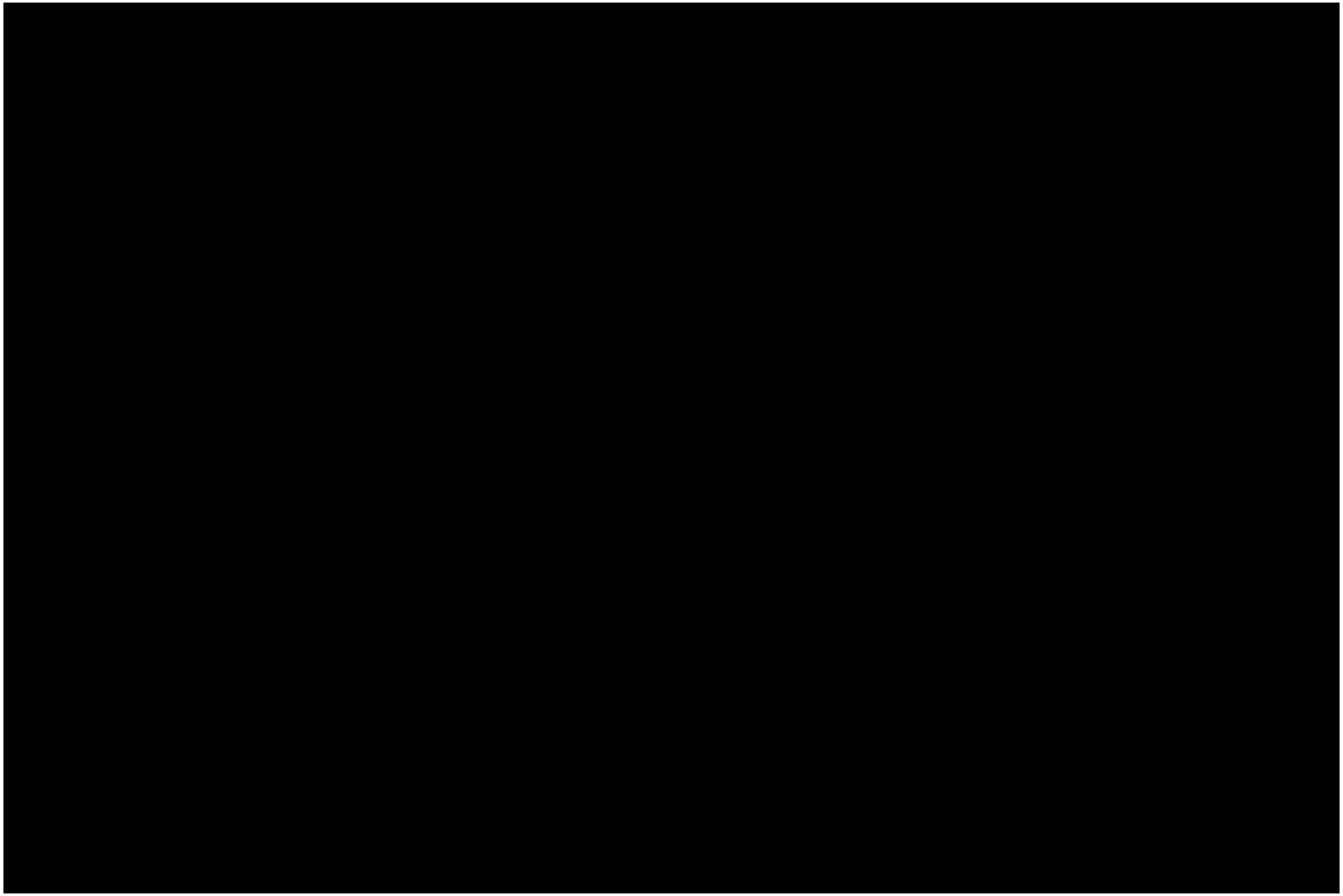
Medical Education – Explosion of Information

- Medical procedures are becoming more numerous and more complex – medical knowledge has "hypertrophied" (Cooke, 2006)
- Training residents to a common level of knowledge and competence is already impossible (Satava, 2008)

"The Perfect Storm" (Murphy, 2007)

- Risk to patient health. (McDougall, 2007)
- Ethics of practicing on patients. (Satava, 2004; Murphy, 2007)
- Cost is a barrier to training. (Bridges, 1999)
- Insurance coverage of educational actions. (Satava, 2004)
- Working hour limits. (Satava, 2004)
- Availability of training opportunities. (Birden, 2007; Davis, 1999)
- Access to training. (Dunkin, 2007; Spitzer, 1997)
- Complexity of modern surgery. (McDougall, 2007)
- Volume of unique procedures. (Reznick & MacRae, 2006)
- Proficiency-based Medicine. (Murray, 2005)
- Quality of technology. (Murphy, 2007)
- Expectations around computer technologies. (Murphy, 2007)
- Acceptance of technology. (Ziv, 2003)
- Learning from Mistakes. (Ziv, 2005)

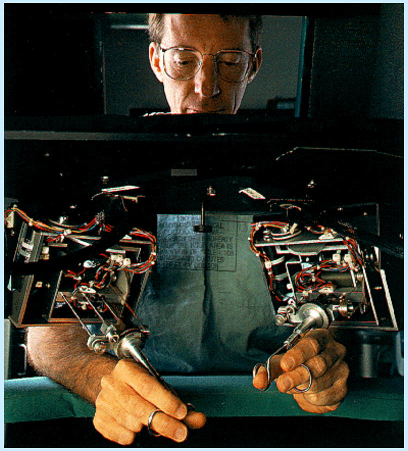
Intuitive Surgical's da Vinci Robot



Video at: http://www.youtube.com/watch?v=0NZLpWrJGgk

Robotic and Telesurgery Research using Simulation

Telesurgery



Comms Latency:
- •Modify surgical procedures
- •Safe Telesurgery at 500ms
- •Match to City-Pairs

Automatic Surgery:
- •Record Surgery in Simulator
- •Execute with Unmanned Robot
- •Identify Control Variables

Simulation

Surgical Rehearsal:
- •Dynamic Organ Model in Sim
- •Patient-specific Rehearsal
- •Improve Surgeon Performance

Military-use Validation:
- •Simulator of Robotic Surgery
- •Retain Skills in Theater
- •Define Deployable Package

Robotic Curriculum

Consensus Conferences:
- •Define Certification Criteria
- •Develop Curriculum
- •Develop Training Tasks

Curriculum Validation:
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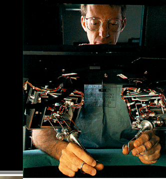
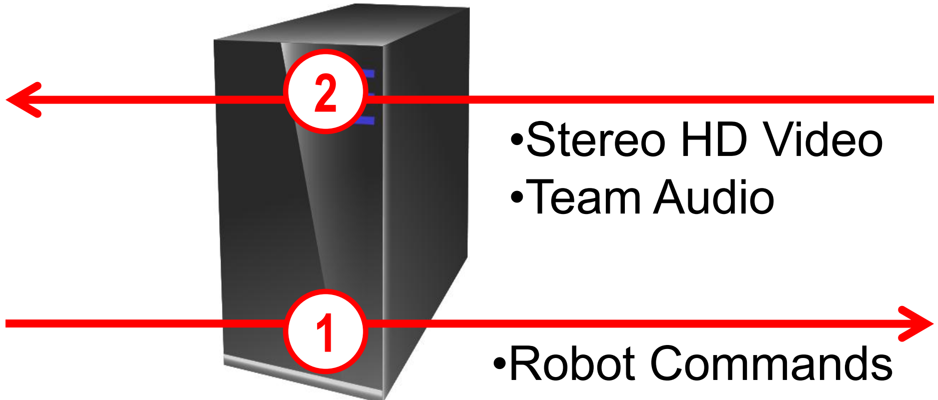
- •Identify Testing Measures
- •Set Passing Criteria

Telesurgery: Communication Latency



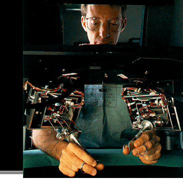


- Stereo HD Video
- Team Audio

- Robot Commands
- Surgeon Audio

Comm Latency = 1 + 2

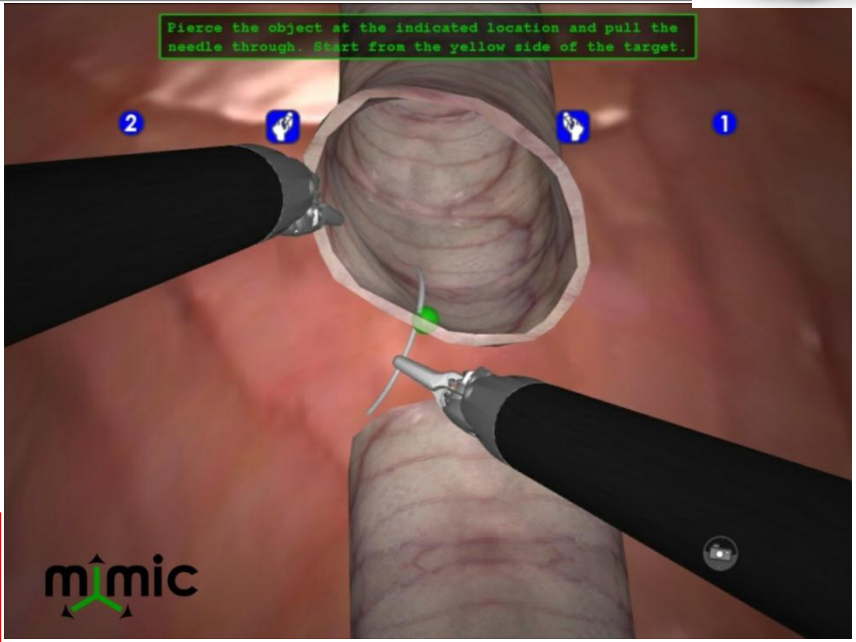
Telesurgery: Simulated Latency



da Vinci Skills Simulator

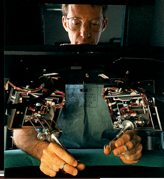
Mimic dV-Trainer

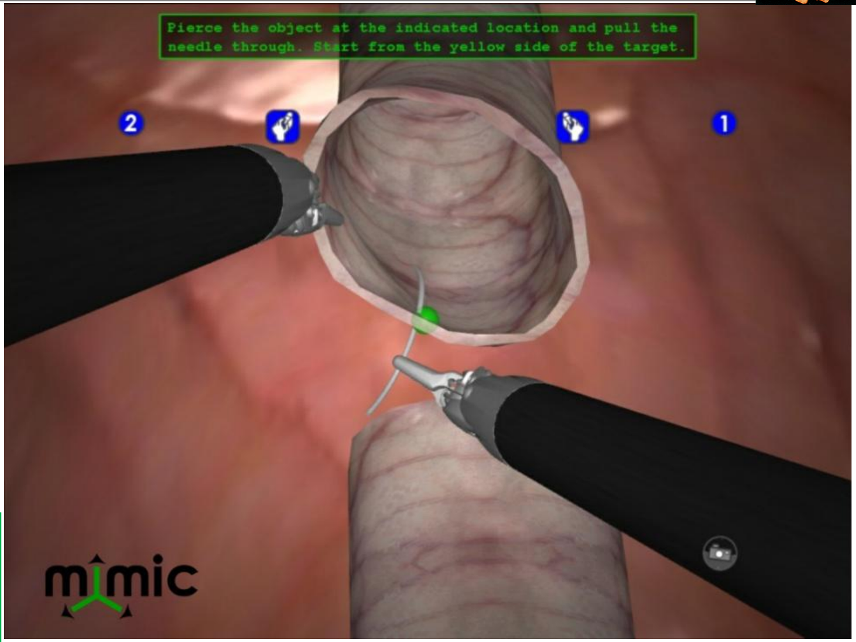
Simulation: Surgical Rehearsal



Skill Trans

Telesurgery: Automatic Surgery





Data Trans

Industry Perspective

- **Simulation as a Research Lab**
  - Simulated environments are a viable and affordable research environment within which to conduct experiments.
- **Simulation for Rehearsal**
  - Simulation is a tool for real-time preparation for surgery.
- **Simulation for Education**
  - Redesign GME surgical courses to include simulators along with classroom and laboratory components.

Fundamentals of Robotic Surgery: Outcomes Measures and Curriculum Development

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Abstract. To standardize the curriculum and certification of robotic surgeons, a series of consensus conferences have been used to compile the outcomes measures and curriculum that should form the basis for the Fundamentals of Robotic Surgery (FRS) program. This has resulted in the definition of 25 specific outcomes measures and the creation of curriculum for teaching those via didactic lecture, psychomotor skills labs, and team training activities. This work has been supported and/or reviewed by the leading surgical societies involved in the use of robotic surgery.

Introduction

In 2004, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) launched the validated Fundamentals of Laparoscopic Surgery (FLS) curriculum and, together with the American College of Surgeons (ACS), promoted the FLS as a minimum standard before a surgeon should be allowed to perform laparoscopic procedures independently [1]. In 2009, The American Board of Surgery (ABS) mandated that in addition to Advanced Cardiac Life Support (ACLS) and Advanced Trauma Life Support (ATLS) a certificate documenting the successful passing of the FLS exam be included in the application in order to be eligible to sit the examination for certification in General Surgery [2].

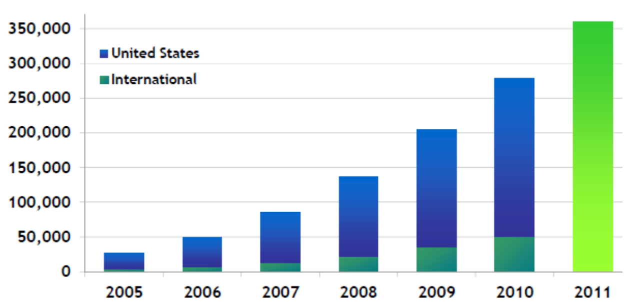

Figure 1. Growing number of robotic surgical procedures
Source: Intuitive Surgical, Inc Investor Prospectus, Feb, 2012

During the last decade, robotic surgery has transitioned through a similar evolution to laparoscopic surgery and is being recognized as an important surgical approach by multiple surgical specialties. Furthermore, it shows every sign of continuing the adoption of more diverse surgical procedures, as manifest by the fact that in calendar year 2011, approximately 350,000 robotic surgical procedures were performed (Figure 1). The number of procedures being performed by robotic surgery has been constantly rising in urology, gynecology, colorectal, pediatric and numerous other specialties. Expert robotic surgeons and numerous surgical societies and certifying organizations have advocated the need for the creation of a unified approach and standardized curriculum for basic training and certification in robotic surgery skills [3]. There have been efforts to develop a core curriculum for certifying robotic surgeons [4,5]; however, these have been fragmented, with different approaches and outcomes measures emerging from each. This has resulted in conflicting, competing and redundant curricula for the training and the assessment tools for robotic surgery. In addition, these curricula have generally lacked the human and financial resources necessary to complete the most comprehensive, multi-institutional validation that is necessary to gain acceptance at a national level.

Through the combined support of two grants, one to the Minimally Invasive Robotics Association and the other to Florida Hospital Nicholson Center, we have created a process and a group of participants which unify the previous attempts to develop a robotic curriculum and expand to a much larger foundation of surgical societies with a stake in this new technology. These grants provide the necessary funding to carry the effort through multi-institutional validation with the support of participants who represent all surgical specialties that are currently performing robotic surgery.

Methods & Materials

Participation in this effort was invited from multiple certifying boards, professional surgical societies, and associations that represent international practitioners and regulators of various surgical specialties as well as the United States Department of Defense (DoD) and Veterans Health Administration (VHA) (Table 1). The conference participants are members of these organizations or agencies and are selected to be able to provide insight into the needs of their organizations, but they do not represent an endorsement or acceptance of the results, and participation does not imply acceptance by the societies, boards or agencies. However, the AUA, AAGL, and SAGES elected to appoint and send representatives who could officially speak for their organizations' needs for a robotic curriculum and officially accept the results of the consensus conferences. This project is an effort to provide the stakeholders with the best scientific evidence upon which to base their decisions regarding implementation of

a fundamental curriculum to meet their needs while reducing redundancy, competition and duplication of effort.

Table 1. Invited Organizational Representation in Fundamentals of Robotic Surgery.

American Association Gynecologic Laparoscopy (AAGL) *
American College of Surgeons (ACS)
American Congress of Obstetrics and-Gynecology (ACOG)
American Urologic Association (AUA) *
American Academy of Orthopedic Surgeons (AAOA)
American Association of Thoracic Surgeons (AATS)
American Association of Colo-rectal Surgeons (ASCRS)
Minimally Invasive Robotic Association (MIRA) †
Society for Robotic Surgery (SRS)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) *
American Board of Surgery (ABS)
Accreditation Council of Graduate Medical Education (ACGME)
Association of Surgical Educators (ASE)
Residency Review Committee (RRC) – Surgery
Royal College of Surgeons-Ireland (RCSI)
Royal College of Surgeons-London (RCSL)
Royal College of Surgeons-Australia (RCSA)
U.S. Department of Defense (DoD) †
U.S. Department of Veterans Health Affairs (VHA)

* : Official Representative Participation
† : Funding organizations.

Each consensus conference was conducted over a two-day period using a modified Delphi method [6]. This methodology consisted of a facilitator who captured the input and guidance of the participants. This input was then analyzed for common concepts to create a list of critical items in robotic surgery. Previously published material from a single institution's curriculum was used as a template for initial idea generation [7,8]. The individual outcomes measures and curriculum materials were itemized and votes taken on their importance according to each participant. This method led to a composite ranking which was captured in a draft report. The report containing the first group ratings was then sent to each participant for their private deliberation. Each participant then submitted a second set of scores which were informed by the first composite scores, but anonymous to other group members. This modified Delphi Method led to a higher level of consensus around the measures and the curriculum. It also identified those items for which there was little group support. Those items were removed from the list of outcomes measures and from the outline of the curriculum.

The first conference on outcomes measures was attended by 20 participants that included surgeons, scientists, educators, and facilitators. The ranking of the tasks identified was done by a subset of nine experienced surgeons. Participants who were not surgeons abstained from the scoring process.

The second conference on curriculum development was attended by 38 surgeons, scientists, educators, and facilitators. This group reviewed and became familiar with the material from the first conference. Thereupon, they were divided into three working groups to develop curriculum that focused on didactic and knowledge-based information, psychomotor skills, and team training and communications. Similarly, the actual ranking of the material developed was limited to experienced surgeons within the group.

Results

The first consensus conference resulted in a list of 25 outcomes measures which the group agreed should be mastered by a surgeon seeking privileges in robotics. These included 8 pre-operative, 15 intra-operative and 2 post–operative tasks which are shown in Figure 2. The resulting report also provides detailed definitions, descriptions, errors, outcomes and metrics for each of these tasks [9].

FRS Outcomes Measures

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

Figure 2. FRS Outcomes Measures.

The second consensus conference on curriculum development resulted in outlines and principles for the creation of a curriculum to teach the previously identified list of tasks and knowledge (Figure 3).

Didactic and Knowledge. The didactic and knowledge working group created an outline of the material which should be taught in lecture format. This will include:

1. Introduction to robotic surgical devices.
2. Pre-operative set-up of equipment and positioning of staff.
3. Intra-operative use of a robot, surgeon ergonomics, visual field control, and necessary instruments and supplies.
4. Post-operative steps for removing a robot and transitioning to bedside control.

Each of these included an explicit list of errors that can occur in the process.

FRS Curriculum Outline

Didactic & Cognitive	Psychomotor Skills	Team Training
Lecture-based	**Principle-based**	**Checklist-based**
Intro to Robotic System	Based on Physical Models (Virtual Models are Derivative)	#1: WHO Pre-Op
Pre-Operative Activity	3D Exam Tools	#2: Robotic Specific
Intra-Operative Activity	Use Tasks that have Evidence of Validity	#3: Undocking & Debriefing
Post-Operative Activity	Multiple Outcomes Measured per Exercise	#4 Crisis Scenarios
Each Activity includes: Goals, Conditions, Metrics, Errors, Standards	Cost Effective Solution	
	High Fidelity for Testing, Lower Fidelity for Training	
	IRR Requires Ease of Administration	

Figure 3. FRS Curriculum Outline and Principles.

Psychomotor. The psychomotor skills working group prefaced their work with seven principles that should be applied in selecting or designing a skills device for robotic surgery. Those principles were:

1. The tasks should be 3 dimensional in nature.
2. The tasks designed for testing should be such that they have multiple learning objectives that incorporate multiple tasks from the first conference report. The tasks designed for training will have more focused learning objectives.
3. Implementation of the tasks and the resultant method for teaching should be cost effective.
4. High fidelity models should be used for testing. Training can use lower fidelity devices or methods.
5. Tasks should be easy to administer to ensure Inter-Rater Reliability (IRR).
6. The tasks should be designed for implementation with physical objects and devices. Future implementation in VR with a simulator would be derivative of the physical model.
7. Preference should be given to tasks that have existing evidence of validity

The group then identified 16 of the 25 tasks which contained psychomotor features. To address these, they proposed ten tasks which could be used to measure these skills. Three tasks were drawn from FLS, others were selected from existing educational programs, and designs for new task devices were proposed.

1. FLS peg transfer
2. FLS suturing
3. FLS pattern cutting
4. Running Suture
5. Dome with four towers
6. Vessel dissection and clipping
7. UTSW 4th arm retraction and cutting
8. Energy and mechanical cutting
9. Docking task (new design)
10. Trocar insertion task (new design)

For each of these the group also identified the associated task description, conditions, metrics, and errors.

Team Training and Communications. The team training and communications working group prefaced their work by defining the importance of team training in a robotic environment. They identified the following principles as essential to successful team-based operations and training.

1. Inclusion
2. Empowerment
3. Person specific
4. Reiterative
5. 'Just in time'
6. Ownership
7. Risk management/quality improvement- closed loop

They stated that existing programs like TeamSTEPPS can be applied to robotic teams. Their curriculum follows a checklist format and is conceptually derived from the standard WHO checklist. For robotic training they recommended the following checklists:

1. Pre-operative. Addressing General situation, surgeon, anesthetist, nurse/OPD, and surgical site infection.
2. Robotic Docking. Addressing anesthesia, patient, bedside assist, procedure-specific checks, and trouble shooting.
3. Intra-operative. Addressing the communication that occurs within a team throughout the operation.
4. Undocking and Debriefing.

A third consensus conference is scheduled for August 2012 to write the detailed material that will be included in the didactic and team training sections of the curriculum; and where specific psychomotor skills devices will be identified, designed and selected.

Conclusions & Discussion

Two consensus conference involving members from major stakeholder organizations in surgical training, governance, and certification across multiple specialties have been conducted to arrive at a consensus regarding the most important outcome measures for the safe conduct of robotic surgery and the curriculum to teach those skills and knowledge. The development of FRS is multi-specialty, system agnostic and follows decades of experience in other industries at developing such education and training platforms. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgery skills and is capable of passing the requirements of high stakes testing and evaluation. At some future time, this testing and evaluation would be administered by an appropriate independent, objective and authoritative organization,

which would adopt the materials developed through this consensus process.

Acknowledgments

This project is a collaboration of leading robotic surgeons and educators. The following have all participated in and contributed to the creation of the materials reported here: A. Advincula; R. Aggarwal; A. Al Ansari; D. Albala; R. Angelo; M. Anvari; J. Armstrong; G. Ballantyne; M. Billia; J. Borin; D. Bouchier-Hayes; T. Brand; S. Chauhan; P. Coelho; A. Cuschieri; B. Dunkin; S. Dunlow; V. Ficarra; A. Gallagher; L. Glazerman; T. Grantcharov; D. Hananel; J. Hebert; R. Holloway; W. Judd; K. Kim; M. Koch; T. Kowalewski; R. Kumar; K. Kunkler; G. Lee; T. Lendvay; R. Leveillee; J. Levy; G. Maddern; S. Magnuson; M. Marohn; D. Maron; M. Martino; P. Neary; K. Palmer; E. Parra-Davila; V. Patel; S. Ramamoorthy; K. Rha; J. Riess; B. Rocco; R. Rush; R. Satava; D. Scott; N. Seymour; M. Sinanan; R. Smith; D. Stefanidis; C. Sundaram; R. Sweet; E. Verrier; G. Weinstein

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NICHOLSON CENTER

Robotic & Telesurgery Research

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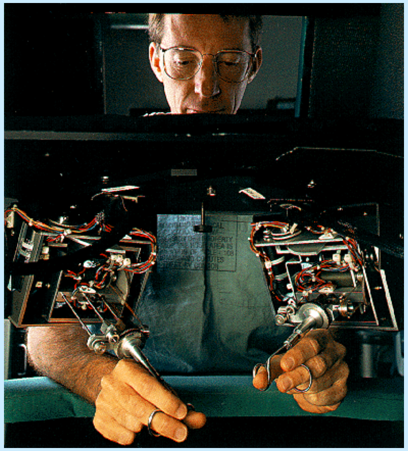
Robotic and Telesurgery Research Summary

Telesurgery



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- Identify Testing Measures
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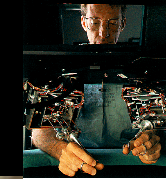
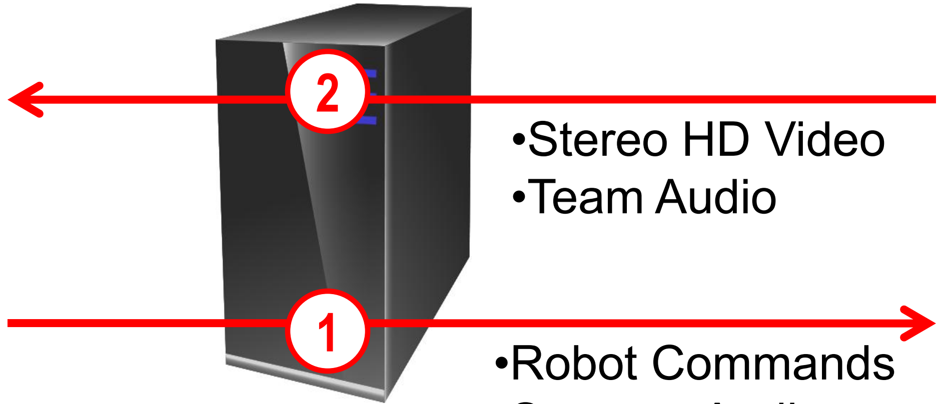
Telesurgery: Communication Latency



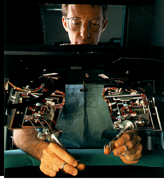


- Stereo HD Video
- Team Audio

- Robot Commands
- Surgeon Audio

Comm Latency = 1 + 2

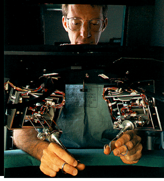
Telesurgery: Simulated Latency

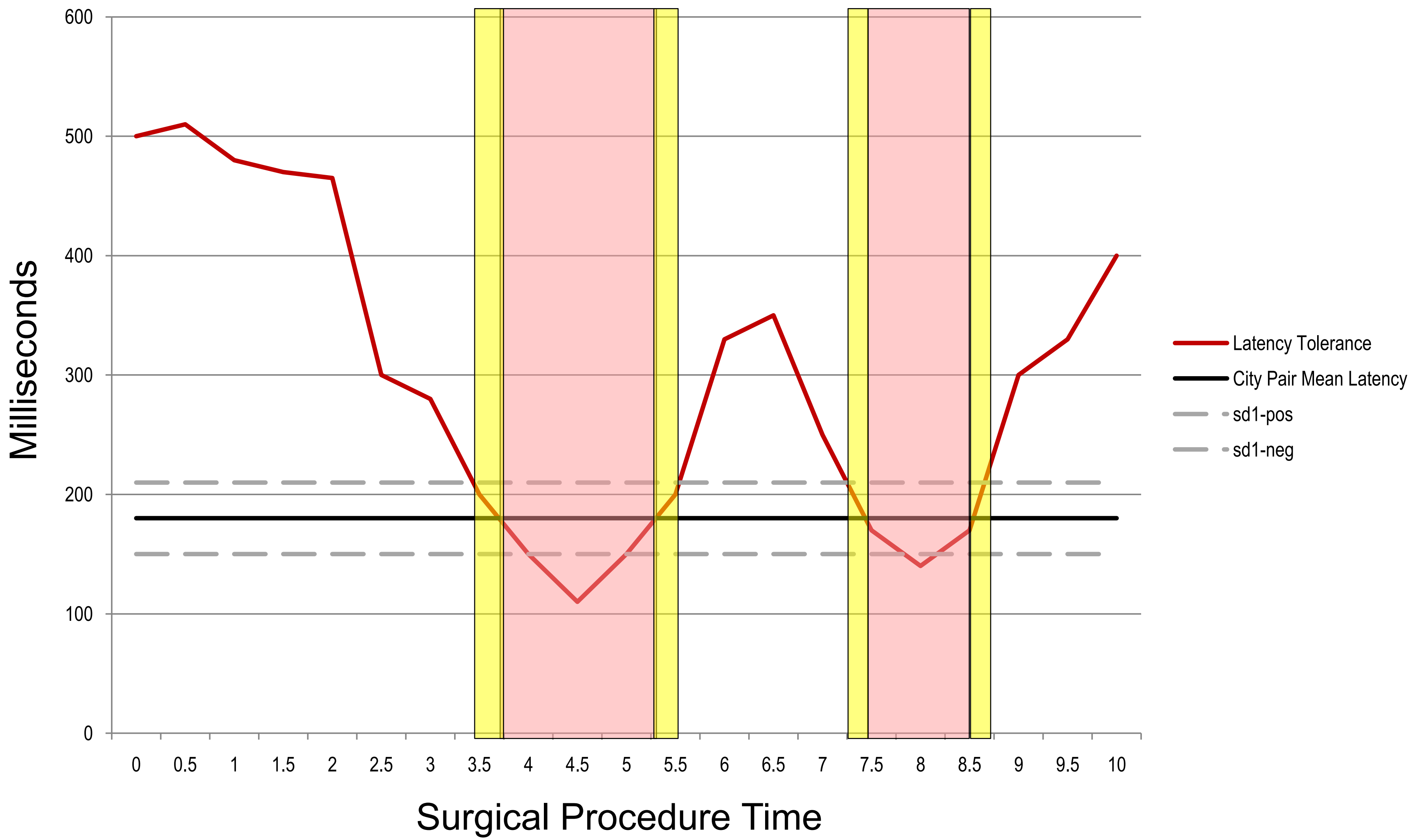


da Vinci Skills Simulator

Mimic dV-Trainer

Telesurgery: Latency Tolerance (Concept)





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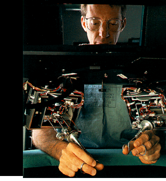
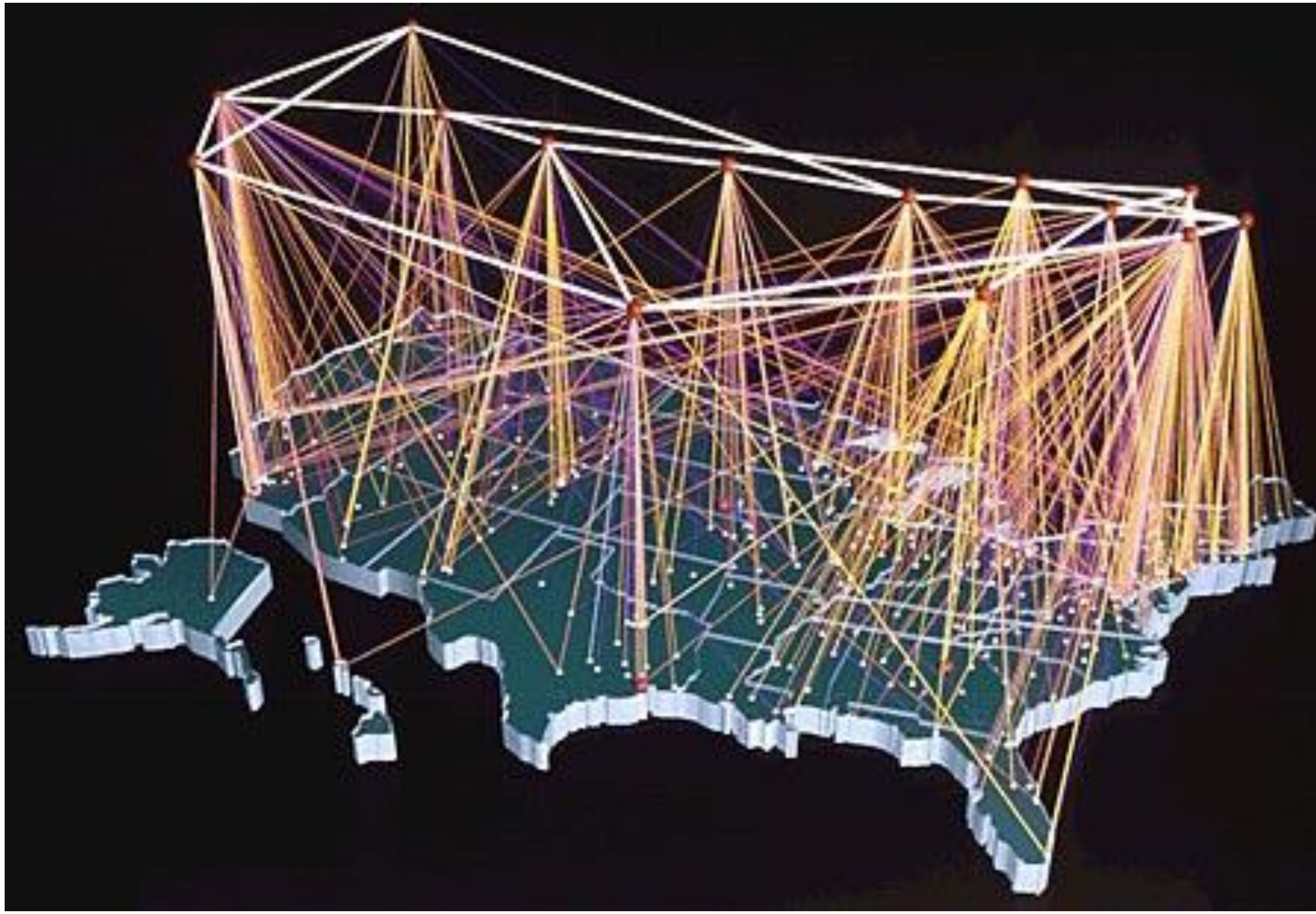
Latency Map: City Pairs

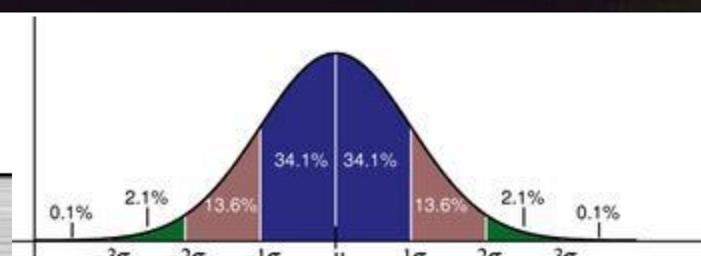




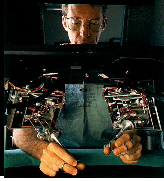
Potential City Pairs:

Orlando, FL
Bethesda, MD
Seattle, WA
Boston, MA
New York, NY
Atlanta, GA
Dallas, TX
Denver, CO
San Fran, CA

Strasbourg, FR
Sao Paulo, BZ
Tel Aviv, IS

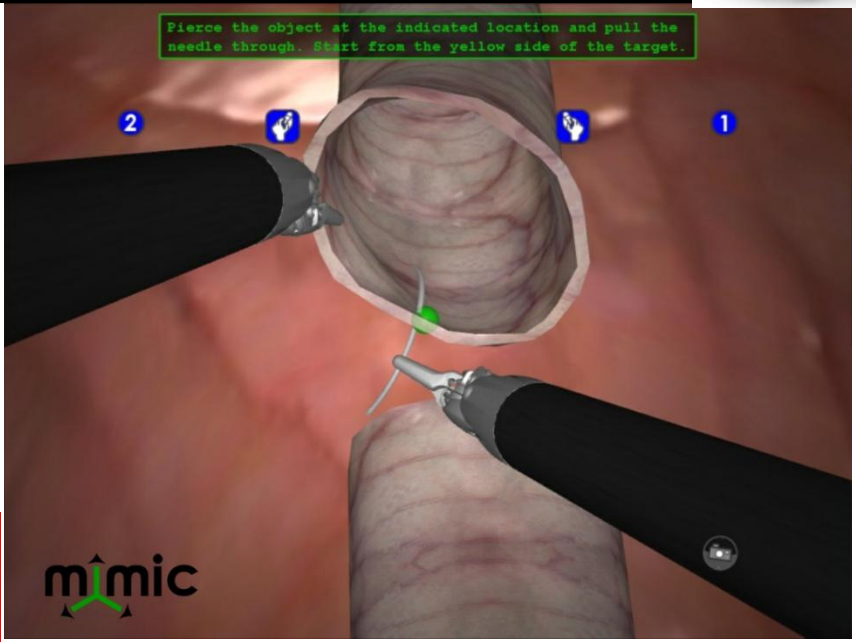


Telesurgery Modifications



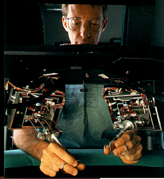
- Control pace of movement
- Subdivide current atomic movements
- Change direction of movements
- Introduce new instruments
- Stabilize tissue
- ….

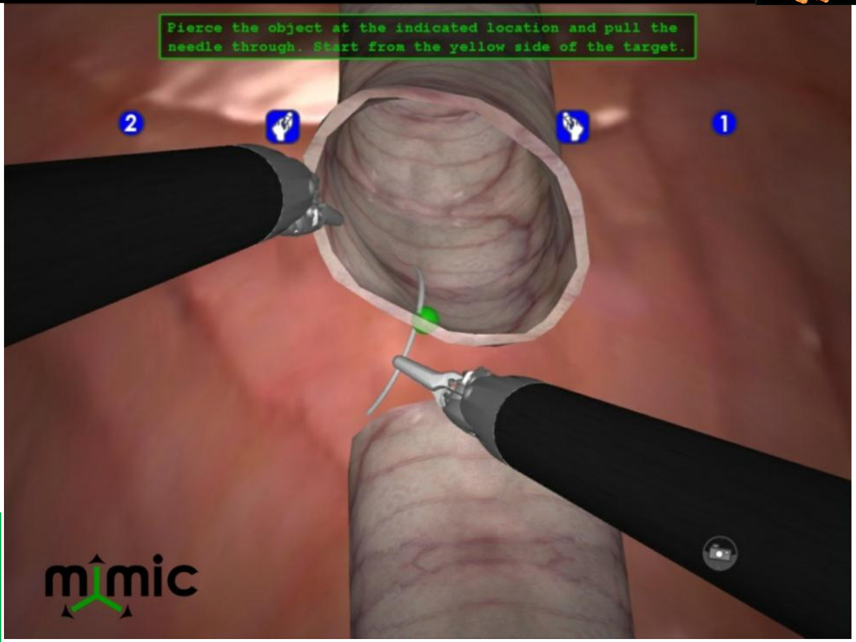
Simulation: Surgical Rehearsal



Skill Trans

Telesurgery: Automatic Surgery





Data Trans

Simulation: Military-use Validation

Robotic Surgery
Skills Retention

Fundamentals of Robotic Surgery

WHAT	Outcomes & Metrics	Course Development	Simulator Development	Validation Studies	Implement: Survey Training Certification	Issue Certification
HOW	Consensus Conference	Standard Curriculum Template	Engineering Physical Simulator	Standard Validation Template	Current Procedures	Issue Mandates And Certificates
WHO	ABS SAGES ACS Specialty Societies	SAGES ACS Societies Academia	Industry with Academia Medical Input	ACS SAGES, Participating Societies	FLS SAGES/ACS	ABS certifier

Future Directions

- **Robotics**
  - Machine assistance for all surgical procedures. “Robot” will take multiple forms to fit the needs of the procedure.
  - Redesigning the operating room to accommodate people, machines, and information.
- **Simulation**
  - Lap and Robotics use equipment to intermediate between the surgeon and the patient. Creates a natural environment for training simulators
  - VR/Games/Browser in providing in-hospital maintenance training. Currently done largely with in-service seminars.
- **Education**
  - Curriculum that integrates lecture, live, and simulation. Nursing has taken the lead in this, surgery catching up.

MANUSCRIPT DRAFT
Submitted to the journal *Surgery*

Fundamentals of Robotic Surgery Consensus Conference 1: Outcomes Measures

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Fundamentals of Robotic Surgery Consensus Conference I: Outcomes Measures

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Abstract

Background: *Robotic surgery has diffused into clinical surgical practice and provides a minimally invasive opportunity for several surgical procedures across multiple specialties. However, no comprehensive basic skills curriculum has been validated to ensure the proficiency of the surgeon who is using the robot. A rigorous, standard methodology is being developed to create a basic robotic surgery skills curriculum called the Fundamentals of Robotic Surgery (FRS). The purpose of this report is to describe the results of the first consensus conference - Outcome Measures –that will serve as the foundation for the full FRS curriculum.*
Methods: *Surgeons from 19 different surgical societies, regulatory bodies and/or federal agencies across multiple specialties were invited to participate in the consensus conference. Among the participants were nine practicing clinical robotic surgeons, 7 professional surgical educators, 8 executive members of surgical societies or boards, 3 representatives from DoD, and 1 representative of the federal government's National Institute for Standards and Testing.* Using a standard task-deconstruction methodology, the group identified the basic tasks and their outcome measures required for robotic surgery. Task importance was rated using a modified Delphi methodology to arrive at group consensus and tasks with a score below 2 standard deviations from the mean were excluded. ***Results:*** *A total of 26 tasks were identified (8 pre-operative, 15 intra-operative and 3 post–operative). After the second round of Delphi voting, the mean score was 28.19 (range: 18-35; SD: 4.94). Situational awareness received the highest score (35) followed by eye hand instrument coordination, needle driving and atraumatic handling (33). Transition to bedside (20) and clip applying (18) received the minimum score. The threshold score was 19.77 and following the final Delphi round, one task (Clip Applying) was excluded from the final task list.*
Conclusions: *The first FRS consensus conference for Outcomes Measures was conducted to identify the candidate tasks and outcome measures for the FRS curriculum development. The final 25 tasks will be used in the next consensus conference on Curriculum Development to guide the development of a standard curriculum. This will be followed by a third consensus conference to design a Validation Study.*

Introduction

The introduction and subsequent adoption of any new technology into clinical practice opens further frontiers for more effective management or even a potential cure for several diseases. However, with the exponential growth of technology in the Information Age, the training and certification of surgeons to perform a new procedure safely and effectively poses a unique challenge. For example, the proliferation of laparoscopic surgery as the new gold standard for symptomatic cholelithiasis initially led to an increase in common bile duct injuries [1-3].This rightfully cautioned the governing bodies, academic surgical community and even surgeons at large to develop methods that would ensure that only competently trained surgeons perform such complicated procedures, which frequently required a different skill set than open procedures.

In 2005, the Accreditation Council for Graduate Medical Education (ACGME) recognized the importance of using simulation in the training and assessment of surgical technical skills and required that by 2008, surgical residency programs have access to a simulation center [4]. In 2004, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) launched the validated Fundamentals of Laparoscopic Surgery (FLS) curriculum and, together with the American College of Surgeons (ACS), promoted the FLS as a minimum standard before a surgeon should be allowed to perform laparoscopic procedures independently [5]. In 2009, The American Board of Surgery (ABS) mandated that in addition to Advanced Cardiac Life Support (ACLS) and Advanced Trauma Life Support (ATLS) a certificate documenting the successful passing of the FLS exam be included in the application in order to be eligible to sit the examination for certification in General Surgery [6].

During the last decade, robotic surgery has transitioned through a similar evolution as laparoscopic surgery and is being recognized as an important surgical approach by multiple surgical specialties. Furthermore, it shows every sign of continuing the adoption of more diverse surgical procedures, as manifest by the fact that in calendar year 2011, approximately 350,000 robotic surgical procedures were performed (Figure 1). The number of procedures being performed by robotic surgery (a standard in neurosurgery and urologic surgery) has been constantly rising not only in urology, but gynecology, colorectal, pediatric and numerous other specialties – hence the inclusion of the many surgical specialties. Expert robotic surgeons and numerous surgical societies and certifying organizations have advocated the need for the creation of a unified approach and standardized curriculum for basic training and certification in robotic surgery skills [7]. Unfortunately, the excellent results of the adoption of FLS has no documentation as to the method of developing the curriculum which could be adapted for the FRS, therefore this manuscript includes a detailed methodology for curriculum development which is intended to not only support the FRS, but subsequent robotic and non-robotic curricula which will be developed within the specialties, providing a common methodology so each time a curriculum is developed it is not necessary to 'reinvent the wheel'. In addition, there have been current efforts to develop a core curriculum for certifying robotic surgeons [8,9]; however, this is a fragmented effort, with different approaches and outcomes measures. This has resulted in conflicting, competing and redundant curricula for the training and the assessment tools for robotic surgery. In addition, these curricula have generally lacked the financial resources necessary to complete the most comprehensive, multi-institutional validation that is necessary to gain acceptance at a national level.

The FRS initiative is a collaboration between the academic community and the federal government to assist in developing an interoperable, uniform curriculum that is acceptable across multiple surgical specialties (Table 1). A major premise is that this curriculum will only address the most basic of skills necessary to safely conduct robotic surgery and that the participating surgical societies will develop respective fundamental robotic surgery curricula that are still very basic but unique to their specialty, such as the Fundamentals of Urologic Robotic Surgery or the Fundamentals of Gynecologic Robotic Surgery. An important concept is that the curriculum template that is used to craft the FRS can

form an interoperable platform for developing, in a modular fashion, the subsequent curricula that are needed for each specialty. This concept, was first presented by Dr. Robert Sweet, Department of Urology, University of Minnesota in 2010 during an ACS Accreditation Educational Institute conference and has been referred to as the "Sweet Tree" of curriculum development (Figure 2).

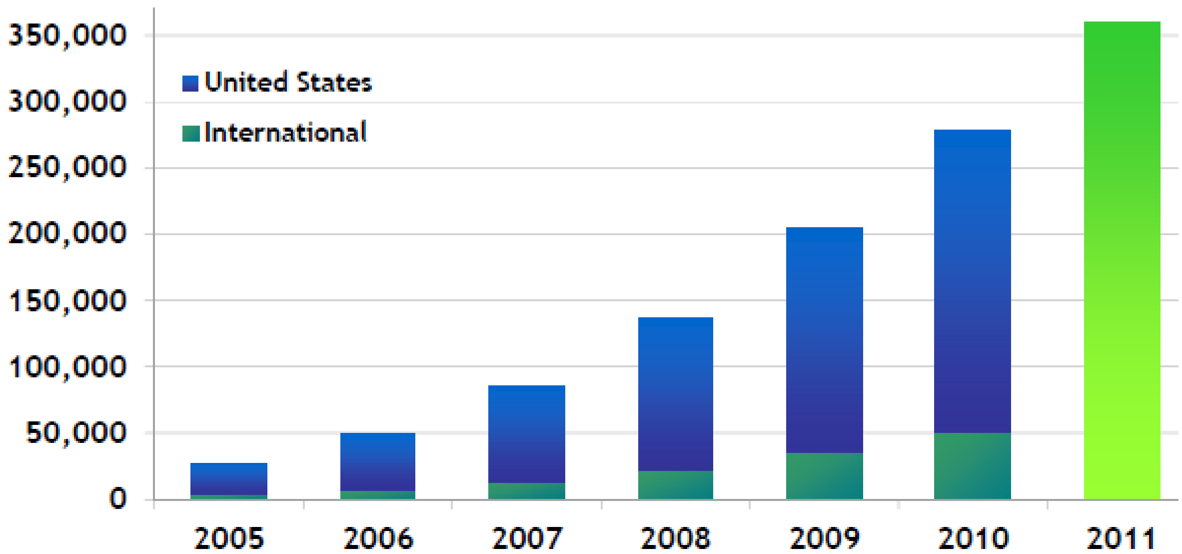

Figure 1 Increase in number of robotic surgical procedures
Source: Intuitive Surgical, Inc Investor Prospectus, Feb, 2012

Table 1: FRS Mission statement, specific goals and deliverables of the consensus conferences.

Mission statement:
"To create, develop and validate a multi-specialty, technical skills and competency based curriculum for surgeons to safely and efficiently perform basic robot-assisted surgery."

Goals:
1. Identify the outcomes measures, which will be required by the curriculum and the methods of measuring them.
2. Integrate how and which process will be used to acquire the outcomes measures.
3. Define the tasks/subtasks that are to be measured using task analysis methods.
4. Match the list of the specific tasks/subtasks with the desired outcomes measurements and how those measurements will be acquired.

Deliverables:
The report of the outcomes measures meeting, to be made available for the next curriculum meeting of FRS, which specifically lists:
1. Appropriate outcomes needed to train, assess, and certify the most fundamental skills in robotic surgery
2. The suggested/preferred methods of measuring/acquiring the metrics
3. The suggested tasks/subtasks for the FRS
4. The actual quantitative/qualitative measures that need to be measured for the individual tasks/subtasks that comprise the FRS

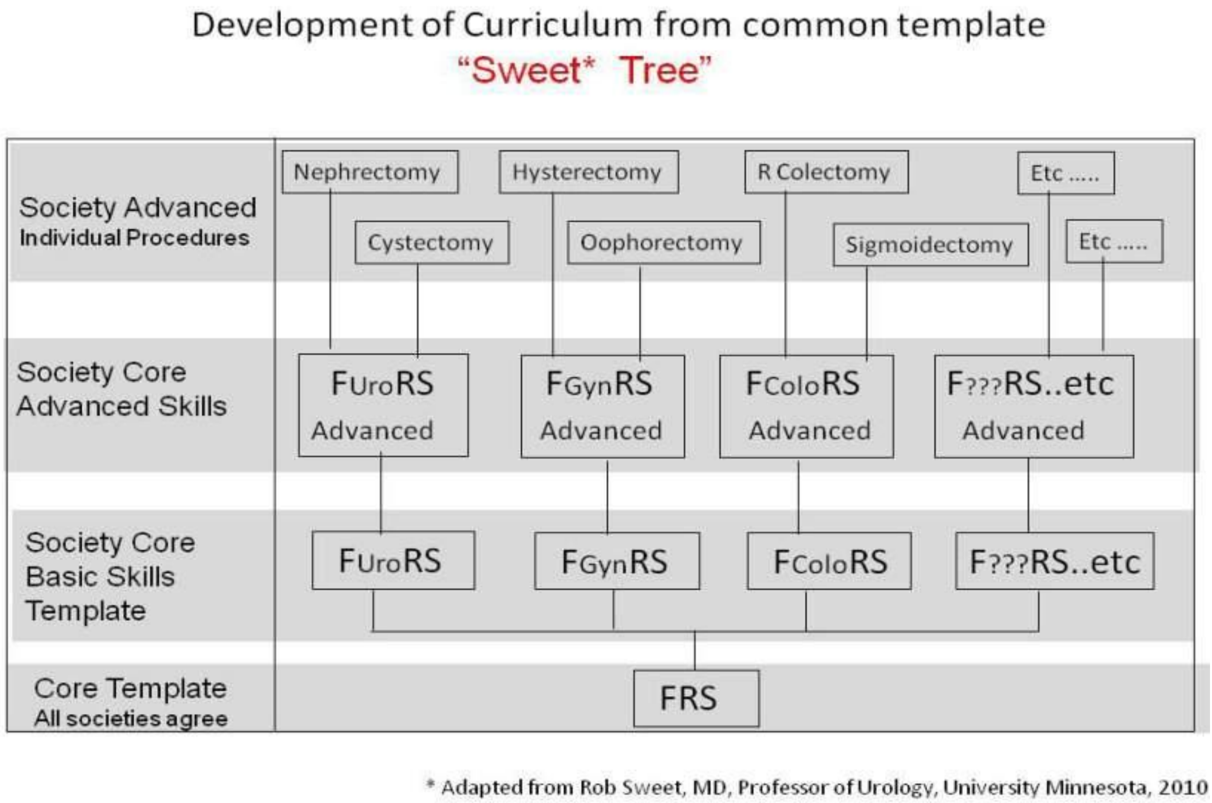

Figure 2. The "Sweet Tree" of curriculum development

The curriculum for FRS is focused on multidisciplinary shared skills at the "trunk" of the tree. It is being designed to be open source, based upon the integrated effort of the various key stakeholders' stated needs. This will be validated in a multi-institutional validation study that will be scientifically stringent enough to meet the criteria of high stakes testing and evaluation such as board certification and recertification for performing robotic surgery. This will be available to societies and certification authorities across multiple specialties. The full life cycle of the FRS curriculum will be developed through a series of at least three consensus conferences: (1) Outcomes measures, (2) Curriculum development and (3) Validation design, (as illustrated in Figure 3) using a "backward design" methodology (analogous to reverse engineering) that has been developed and iterated by the non-medical education and simulation community over the past 80 years [10]. The purpose of this manuscript is to report the results of the first consensus conference in the series, which was held on December 12th and 13th, 2011 at the Florida Hospital Nicholson Center (FHNC).

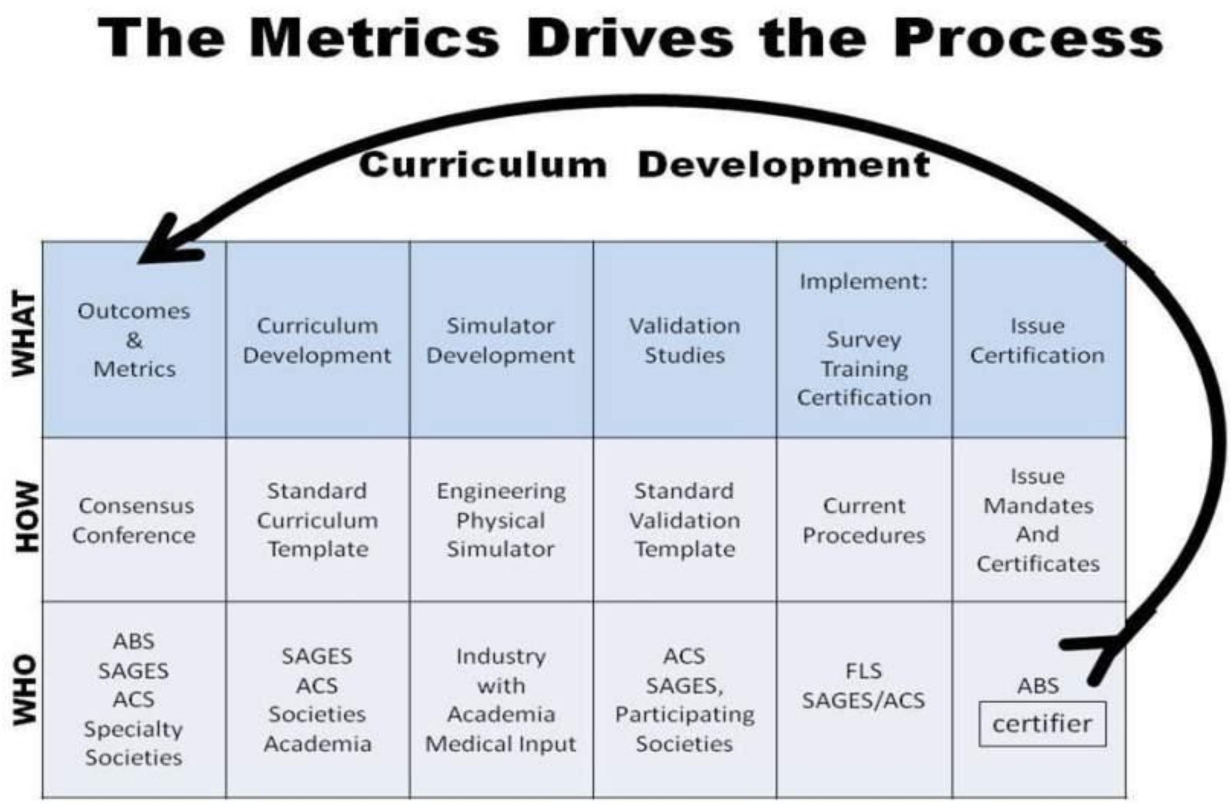

Figure 3. The metrics drive the process: Full life cycle development of a curriculum

Material and Methods:

Participating organizations: Invitations to participate in the consensus conferences were sent to a wide variety of stakeholders which included multiple certifying boards, professional surgical societies, and associations that represent practitioners and regulators of various surgical specialties and the United States DoD (Table 2). While the conference participants are members of these organizations or agencies and are selected to be able to provide insight into the needs of their organization, they do not represent any endorsement or acceptance of the results, and participation does not imply explicitly or implicitly, any level of acceptance by the societies, boards or agencies. However, the AUA and AAGL elected to appoint and send official representatives to speak for their organizations' needs for a robotic curriculum and officially accept the results of the consensus. It is the intent however that many appropriate stakeholders would be willing to review the results of the final validated curricula and choose to implement it in a manner that would be acceptable to their standards and principles. This process is a grass roots effort to provide the stakeholders with the best scientific evidence upon which to base their decisions regarding implementation of a fundamental curriculum that can help create a uniform approach to curriculum development that is efficient, cost effective and flexible enough to meet their needs while reducing redundancy, competition and duplication of effort.

Table 2: Organizations invited to send representatives.

American Association Gynecologic Laparoscopy (AAGL) *
American College of Surgeons (ACS)
American Congress of Obstetrics and-Gynecology (ACOG)
American Urologic Association (AUA) *
American Academy of Orthopedic Surgeons (AAOA)
American Association of Thoracic Surgeons (AATS)
American Association of Colo-rectal Surgeons (ASCRS)
Department of Defense Central Simulation Committee (CSC)
Minimally Invasive Robotic Association (MIRA) †
Society for Robotic Surgery (SRS)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
American Board of Surgery (ABS)
Accreditation Council of Graduate Medical Education (ACGME)
Association of Surgical Educators (ASE)
Residency Review Committee (RRC) – Surgery
Royal College of Surgeons-Ireland (RCSI)
Royal College of Surgeons-London (RCSL)
U.S. Department of Defense (DoD) †
U.S. Department of Veterans Health Affairs (VHA)
* : Official Representative Participation
† : Funding organizations.

The modified Delphi method The Outcomes Measures Workshop was conducted over a two-day period using a modified Delphi method [11]. This typical methodology consists of a facilitator who works with the participants in large sessions and smaller break-out groups to capture the ideas and suggestions generated by the participants. For our conference, the ideas were then analyzed for common concepts to produce a list of critical items in robotic surgery. A previously published tasks deconstruction list from a single institution's curriculum was used as a template for initial idea generation [12, 13]. The individual items were then prioritized by value, rank-order, or sequence in a preliminary table, graph or narrative form. From each session, a 'reporter' was chosen from the group to summarize and deliver the results of the session to the group as a whole for further refinement. The final session of the conference was a review of the consolidated results and final comments and critique by the participants. Following the conference, the first draft of the report was generated by the principal investigators of the program and a second round anonymous Delphi rating was used to achieve greater concurrence, to prioritize the ranking of the tasks, and to eliminate low-scoring tasks.

Scoring method: The first round of voting was carried out in an open forum with participants indicating their opinion on the importance of the task on a four point scale, where 1 = not important, 2 = somewhat important, 3 = important, and 4 = critically important. The votes were tallied in the task matrix and a total score was computed by multiplying the scoring level by the number of votes at that level and summing across all levels.

$$TotalScore = \sum Rating_i * NumVotes_i$$

The tasks were then rank ordered based on each of their Total Scores where a higher score results in a higher order in the ranking. In the event of ties in the total score, the tasks received sequential places in the ranking. This ranking identified the level of support that existed within the group. The results were compiled into a Task Matrix (Table 3) which identified the tasks, definitions, error conditions, measurement methods, importance scores and ranking within the group.

Table 3. FRS Task List, Ranked Ordered by Total Score, Following 2nd Round Delphi Scoring

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient-Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view.	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	0	1	8	35	1
Eye-hand instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments.	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion	0	0	3	6	33	2
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, Needle damage, Needle positioning, Needle dropping, Holding out of field-of-view, Poor accuracy	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	3	6	33	3
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials	Metric-respect for tissue, Stress and strain indentation and	0	0	3	6	33	4

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
	or surgical material without crushing or tearing. Respect to tissue		without damage	deformation						
Safety of Operative Field	Appropriate insertion and positioning of instruments.	Instrument collision with tissue outside of field-of-view	Effectively avoids instrument collision and damage with tissue outside of field of view	Instrument to tissue contact, tissue damage	0	1	2	6	32	5
Camera	Maneuvering the camera to obtain a suitable view	Not focused, Wrong distance to tissue, Inappropriate field of view, Disorientation on camera orientation, Inappropriate choice of camera angle, Camera contact with tissue	Maintains optimal imaging, including horizontal orientation, field-of-view, angle at all times.	Time, efficiency(clutching), sizing(magnification and field of view), horizontal orientation, camera tissue contact, control and manipulation, smoothness, scope angle selection	0	0	4	5	32	6
Clutching	Maintaining comfortable range of motion for manual controls	[Extension of Ergonomics] Loss of range-of-motion	Efficiently maintains full range of motion at all times, in an ergonomic manner.	Joystick collisions, joystick maintained within fly zone(establish what fly zone is), efficient control system usage(excessive clutching, wrong pedal)	0	1	2	6	32	7
Dissection – fine & blunt (Traction/ counter-traction)	Using instruments to perform precise or blunt dissection of structures	Failure to identify correct tissue plane, Inadequate traction/counter-traction, Reversing blunt vs. fine	Performs dissection in appropriate planes with suitable traction/counter-traction and without collateral damage	Accuracy and damage to surrounding structures, distribution of force across tissue, time,& provides adequate exposure of target tissue	0	0	4	5	32	8
Closed loop communication	Definitive communication techniques between the members of the	Communication failure, Incorrect terminology	Actions match intent between team members. Use of names, individual	Use of names, clarity of request, response time, call back requested and provided	0	0	5	4	31	9

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
	surgical team.		responsibilities given, follow-up information provided.	(TeamSTEPPS®)						
Docking	Surgeon guides OR nurse in positioning bedside robot and attaches arms to trocars	External collision, Misalignment, Bed movement post-docking	Appropriately docks robot in timely fashion with minimal adjustments.	Time to dock, adjustment , patient or instrument collision, robotic arm position, alignment	0	1	3	5	31	10
Knot tying	Exactness of the creation of a knot with suture.	Air knot, Knot slippage, Insecure knot, Inappropriate tail length, Bunny ears, Too tight, Tissue ischemia	Ties secure knots appropriately, accurately and efficiently without tissue damage	Time, economy of motion, tissue damage, material damage, knot location, air knot, knot security, protocol violation, appropriate tail length	0	1	4	4	30	11
Instrument exchange	Changing out instruments used in the operation	Tissue collision during exchange, Non-visualized or memory-guided instrument insertion, Inserting or removing the wrong instrument	Efficient, accurate and safe instrument exchange without tissue collision.	Tissue damage, time, economy of motion, connection to energy source, coordination with assistant, instrument selection, recognition of instrument failure, proper instrument engagement to robotic arm and port, memory recognition, trouble shoot protocol	0	0	7	2	29	12
Cutting	Using the scissors to cut at a precise location	Cutting the wrong structure, Past-pointing, Inappropriate instruments	Accurate and efficient division of target structure without collateral damage	Accuracy, lack of tissue damage, timeliness	0	1	5	3	29	13
Energy sources	Activation and control of cautery or other energy sources	Mirror FLS errors, Pedal to instrument discordance, Activate energy before tissue contact, Unintentional energy activation, Unintentional	Appropriate choice and use of energy sources with no collateral damage.	Collateral tissue damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy use (air burns), pedal selection	0	2	4	3	28	14

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
		energy arcing								
Foreign body management	Removal of all foreign bodies from the operating space.	Failure to confirm foreign body removal (needle, sponge, bulldog)	Safe, appropriate and confirmed foreign body removal	Instrument selection for removal, correct instrument, sponge and needle count, removal technique, immediate confirmation of removal	1	1	3	4	28	15
Robotic trocars	Safe insertion technique.	Incorrect remote center, Trocar slippage, Spatial orientation, Blind insertion (2nd and later), Organ injury, Access will mirror FLS	Appropriate trocar insertion and positioning relative to target and other trocars, without unintentional tissue contact. Maintaining positioning.	Time, tissue damage, number of adjustments, remote center placement, distance between trocars, trocar spatial relationship to target	0	2	4	3	28	16
Suture handling	Running and interrupted sutures (separate or combined)	Breaking suture, Fraying suture, Tissue tearing, Inadequate following, Poor tension, Inadequate tissue coaptation, Inadvertent locking	Appropriate handling of suture material without fraying, breakage, or tissue damage.	Tissue damage, time, accuracy, economy of motion, material damage	0	2	5	2	27	17
Wrist articulation	Understanding and utilizing the full range of motion of the endowrist	Not using all degrees-of-freedom, Inadvertent trapping of tissue or suture	Uses all degrees of freedom appropriately	Time, dexterity and economy of motion	0	2	5	2	27	18
Ergonomic positioning	Positioning of the surgeons torso, arms and feet.	Poor posture, elbow placement	Maintains appropriate posture and ergonomics throughout the operation and minimizes fatigue.	Work load, posture, muscle fatigue	0	1	8	0	26	19
System settings	Setting up and adjusting console settings as needed during	Improper console settings, Scope angle selections, Magnification	Appropriate console settings with minimal ongoing adjustments	Number of adjustments, correct console settings, checks settings, time	0	2	6	1	26	20

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
	surgery	setup, Motion speed/scaling								
Multi-arm control	Activating the fourth arm through clutching and using it in the operation	Collision, Moving wrong arm	Efficient use of multi-arm control without collisions	Time and number of collisions	0	3	4	2	26	21
Operating Room (OR) set-up	Placing the bedside cart in the location where the operative field is most accessible	Incorrect support equipment placement, Breaking sterile field	Proper placement of equipment in a sterile and safe fashion	Breaks in sterile protocol, equipment placement, access and visualization for assistant, time, time to conversion, access/clearance to patient cart for rapid undocking	0	3	6	0	24	22
Respond to robot system error	Understand the robotic protocol	Protocol violation	Identifies correct troubleshooting algorithm and applies steps in a timely fashion to correct the error. Avert unnecessary conversion.	Protocol violations, algorithm identification and correct response, time	1	2	5	1	24	23
Undocking	Removal of robotic equipment from the trocars and patient	Undocking without instrument removal, Tissue damage	Safe and efficient undocking of cart in routine and emergency situations	Time, protocol violation, tissue damage, collisions	0	6	2	1	22	24
Transition to bedside assist	Instrument removal	Tissue damage, Lack of port-site inspection	Safe and efficient removal of instruments and ports	Time, inspection of port sites, bleeding, tissue damage	0	7	2	0	20	25
Clip applying	Accurate application of clips.	Cross-clipping, Short-clipping, Poor accuracy, Inadequate coaptation	Places the clips accurately, appropriately and securely without crossing and without leakage	Time, accuracy, crossed clips, clip damage, incomplete and ineffective clip placement	2	5	2	0	18	26

Second round Delphi voting. After the conclusion of the conference, the task matrix was edited, the scores compiled, and the rankings assigned. The compiled results were emailed to the members of the group for the next step in the process. Each member considered the first round scores and rankings of the tasks in private, and submitted a new vote on the importance of each task using the same scoring scale. The second vote was then compiled and the scores were examined to determine whether the second Delphi round significantly changed the total score and ranking for each task.

Eliminated tasks. Tasks that received a total score more than two standard deviations below the mean score were then tagged for elimination from the list. These tasks will not be included in the ongoing development of a curriculum or validation.

Results. Nineteen participants attended the two-day conference that was organized at FHNC. The surgeons within the group had been in clinical practice for a median of 15 years (IQR: 9-24 years), all of which have been actively involved in simulation research, administration, or training for a median of 10 years (IQR: 9-13.5 years). Finally nine surgeons who actively practiced robotic surgery participated in the voting.

A total of 26 tasks were identified during the workshop (8 pre-operative, 15 intra-operative and 3 post–operative). Following an initial group discussion the definitions, description, errors, outcomes and metrics for each task were defined.

After the first round of Delphi voting, situational awareness, eye-hand instrument coordination and needle driving received the highest score of 32.These were followed by camera maneuvering, clutching, atraumatic handling, knot tying and safety of operative field which each received a total score of 31. Following the face-to-face conference, a final round of voting using a modified Delphi Method was conducted via email. The voting members received the original list with the initial rank ordered list of the tasks, along with a basic statistical analysis of the distribution of those scores. They were asked to vote again on the rating of each task to see if the knowledge of the group scores and the associated ranking of the tasks would cause them to change their score. After the second round of scoring, the mean score was 28.19 (range: 18-35; SD: 4.94). Situational awareness maintained the highest score of 35, followed by eye-hand instrument coordination, needle driving and atraumatic handling (33). Transition to bedside assist and clip applying received the lowest scores of 20 and 18 respectively (Table 3). The threshold score to be included in the outcomes measures (Mean minus two standard deviations) was 19.77. Based on this threshold clip applying was eliminated.

Discussion. The purpose of this workshop on Outcomes Measures was to define the outcomes needed to develop, and subsequently to be used to validate, the FRS curriculum. The recommendation is to use the rank-ordered task list (Table1) as the outcomes measures which are judged as the most critical in defining competency in robotic surgery skills, within the context of patient safety. The list in Table 3 contains the outcomes measures that will drive the second conference on Curriculum Development. The list identifies the most basic tasks needed to develop a FRS curriculum to teach the skills necessary to use a robotic surgery platform safely, regardless of surgical specialty. While it is difficult to predict what new surgical robotic platforms will emerge, the outcomes measures from this conference, along with the subsequent curriculum, will be the foundation upon which the cognitive, psychomotor and team training skills will be tested for robotic surgical platforms.

Previous curricula on technical skills have had the shortcoming of not being adopted by regulatory authorities. Those metrics and curriculum content were developed by only one or two clinical experts whose perspective focused entirely upon the skill or procedure to be taught, and not on the larger needs for patient safety, which is a major concern for regulatory authorities.

Currently it is acknowledged that the majority of robotic surgery is practiced on the da Vinci robotic surgical system (Intuitive Surgical Inc, Sunnyvale, CA). As a result, most surgeons' experience, and immediate future expectation for clinical practice, is with that device. While there may be the perception that the FRS is focused upon this particular robotic surgery system, this is not the case. There are a number of basic principles that apply to any robotic system that will be developed – for example, all robots must be initialized (set up, adjust scaling, etc), must be docked (either next to the patient, above the patient or attached to the table), use a clutching mechanism to navigate the operative field with multiple instruments), perform specific tasks or activities (regardless of the input device or end effectors), have communication with other team members (team training) and safely undock the system. To that end, the outcomes measures were designed to be device agnostic and it is with appreciation that the decades of developing generic flight simulation by the DoD contributed to the approach and design of FRS. However, the working group recognized the widespread adoption of a specific system to date and made conscious decisions to avoid proprietary specifications while acknowledging the importance that the curriculum be capable of evaluating the skills that are currently being used in the operating room.

Several members of the consensus group are aware of the development of surgical robots by other companies and in other countries, but none of these members have direct experience with these devices which they can share with the group. Therefore, attempts to address the operational characteristics of these prototype devices would be purely speculative and inappropriate for a standard curriculum in robotics at this time, yet it was felt that emerging systems will need to address the tasks indicated in this version of FRS. The evolving nature of robotic surgery will necessitate future revisions of this material to capture the variations in devices and procedures that will emerge in the future.

Over the past two decades, it has become apparent that engagement of the organizations with the appropriate authority for standards (e.g. the ACGME, Residency Review Committees (RRC), the American Board of Medical Specialties (ABMS)) ,surgical education and training (the numerous surgical and subspecialty societies, such as ACS, SAGES, AAGL, AUA) and certification (respective surgical and specialty Boards) are critical to the development of a curriculum that is meaningful and acceptable to all individuals and organizations involved in the "full life cycle" of training . The example in Figure 3 of one current model for such a full life-cycle curriculum demonstrates that the initial step for any curriculum is to establish the appropriate Outcomes Measures. It should be noted that this life cycle process requires that there be continuous long-term feedback from the regulatory and certification authorities such that iterative improvement of the curriculum can be achieved over many years, referred to as the 'longitudinal maintenance of a curriculum' over time. It is acknowledged that all stakeholders may or may not initially agree to require such a curriculum. However their input at this time is essential to ensure that, if over time, any organization would want to reconsider and require such a curriculum, that organization would have had input into the creation of the curriculum. It is evident that participation by multiple specialties provides the essential broad perspective that could create a stronger curriculum, whether it is adopted now or in the future.

Our approach to begin the curriculum development with an initial outcomes measures conference was inspired by the ACGME and ABMS establishing the six competencies before beginning the task of developing the educational and training curriculum that will be needed to teach the competencies. It is noteworthy that the above ACGME competencies are inclusive of all medical specialties. In a similar fashion, this FRS curriculum is intended to serve most all surgical and procedural specialties that currently use or have the future potential to perform robotic and computer assisted interventions. It is anticipated that, if created within a framework of a more comprehensive utilization, the process and perhaps the curriculum template will be adopted by the participating specialties to develop their own "specialty unique" fundamentals of robotic surgery. This concept of an initial

template upon which subsequent curricula can be easily developed has been proposed by Dr. Robert Sweet as noted above (Figure 2). The advantages of using a common template are twofold:

1. Comparative Effectiveness Analysis - Across specialties. A common process would permit a more scholarly and scientifically valid way of performing comparative effectiveness analysis of outcomes for the identical or similar robotic procedures, especially if two specialties perform the same procedure. In addition, some of the most basic types of procedural skills (such as open, laparoscopic, flexible endoscopic, and image guided) can also be developed and adopted with a uniform methodology, as the FRS has the potential to do, thus saving resources by eliminating the need for every society to develop their own variation of skills. This also provides a 'de facto standard' that could be applied towards a more uniform way of developing curricula.
2. Comparative Effectiveness Analysis - Within a specialty. Such a common process would allow much easier development of subsequent, more-complicated, specialty curricula, as indicated by the Sweet Tree. It will also be possible to conduct a more scientific validation of a comparative effectiveness analysis of the same procedure using different techniques (such as robotic versus laparoscopic versus open surgery).

This methodology has been successfully executed within other non-medical simulation environments, and has enabled sharing of basic elements of curriculum development, validation, and certification. This has resulted in saving time and resources by eliminating competition and redundancy. The last point warrants emphasis, because simulation is new to healthcare, and much can be learned about simulation and curriculum development from the more than eighty years of experience in the aviation, military, and nuclear domains. While each of these domains is unique, it is the process and methodology that has allowed for a much more efficient development of training curricula. As a first initiative, it is anticipated that constructive changes will occur in this curriculum as feedback is used to improve this initial effort.

Material developed under FRS in this work focused on measuring the most basic skills that a surgeon must possess in order to perform robotic surgery. Although some of these skills require a background of general surgical knowledge, most measures of competency in FRS focus on cognitive and psychomotor technical skills. The scope was limited to actions performed by the surgeon in preparing, performing, and finishing a robotic procedure. These have included the most common errors that are committed in each of these areas. The actions of the entire surgical team were not part of this evaluation, though team leadership and performance were recognized as critical. The surgeon's role within that team was included.

Conclusions: The consensus conference involving members from major stakeholder organizations in surgical training, governance, and certification across multiple specialties was conducted to arrive at a consensus regarding the most important outcome measures for the safe conduct of robotic surgery. It is anticipated that the results of the first FRS consensus conference will be used by the Curriculum Development Consensus Conference and will have iterative improvement by clinicians that will be attending that conference. The development of FRS is multi-specialty, system agnostic and follows decades of experience in other industries at developing such basic education and training platforms. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgery skills and is capable of passing the requirements of high stakes testing and evaluation. This testing and evaluation would be conducted by an appropriate independent, objective and authoritative organization, which will adopt the materials developed from this consensus process.

Acknowledgements
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Title

Report on the First Consensus Conference on the Fundamentals of Robotic Surgery: Outcome Measures

Authors

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Abstract

FRS Mission Statement:
"Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery."

Purpose: On 12-13 December, 2011 the Fundamentals of Robotic Surgery (FRS) Consensus Conference (FRSCC#1) on Outcomes Measures convened an international body of leaders in robotic surgery to define the skills necessary to begin the process of creating a certifiable curriculum and testing method in robotic surgery.

Goals: To identify the outcomes that must be measured to certify that a surgeon has the most basic of cognitive and psychomotor technical skills for robotic surgery. These outcomes are organized as a list of tasks that a surgeon must be able to perform successfully, a list of the most common errors associated with each task, and the metrics that will be used to measure competency in that task.

Objectives: To develop a list of skills, tasks and errors critical to the performance of robotic surgery, and identify quantitative outcome metrics that accurately measure performance.

Scope: Material developed under FRS in this work focused on measuring the most basic skills that a surgeon must possess in order to perform robotic surgery. Although some of these skills require a background of general surgical knowledge, most measures of competency in FRS were technical (both cognitive and psychomotor) skills specifically required and essential to robotic surgery.

The scope was limited to actions performed by the surgeon in preparing, performing, and after finishing a robotic procedure as well as the more common errors in each of these areas. The actions of the entire surgical team were not part of this evaluation, though team leadership and performance were recognized as critical. The surgeon's role within that team was included.

Methodology: The Consensus Conference was conducted during a 2 day period using a modified Delphi methodology. The participants consisted of subject matter experts from 14

different surgical specialties that use robotic surgery, as well as representatives from a number of the certifying surgical specialty boards and surgical education societies, and included participation by the civilian, the Department of Defense and the Veterans Administration (VA) sectors. Many of the participants are members of the ACS-AEI and of the Alliance of Surgical Specialties for Education and Training (ASSET). After the evaluation of existing materials and curricula, a task deconstruction was performed to identify the tasks, subtasks and errors that need to be measured. A matrix was then created that matched metrics to the tasks, skills and errors.

Following the conference, a second round classic Delphi anonymous rating was used to insure concurrence, to prioritize the ranking of the tasks and to eliminate low-scoring tasks.

Results: The results provide a matrix of specific robotic surgery tasks that are matched to their common errors, a description of the desired outcome and the quantitative metrics that support those outcomes. These tasks are the core material that will be presented at this meeting.

Future Directions*:* The measures that are the results this conference will be utilized as the requirements for metrics that must be incorporated into the curriculum development at the FRSCC#2 Curriculum Development conference. Following the completed curriculum, there will be a FRSCC#3 Validation Study Design conference, the design of which will be utilized in the multi-institution Validation Study.

Upon completion, the validated curriculum will be transitioned to the Fundamentals of Laparoscopic Surgery Committee of SAGES/ACS to develop the high-stakes testing and evaluation and eventually submitted to appropriate certifying boards for consideration of adoption.

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ACS-AEI Meeting, Chicago, IL, March 26, 2012

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